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<p>1 computed based on your methodology, the</p> <p>2 rate of pain with the autologous slings</p> <p>3 was actually higher than the midurethral</p> <p>4 sling; do you remember that?</p> <p>5 A. Leg pain?</p> <p>6 Q. You didn't break it down by</p> <p>7 leg pain, you just wrote pain.</p> <p>8 A. Is whatever an answer? I'll</p> <p>9 just say whatever.</p> <p>10 Q. Bladder perforation, you see</p> <p>11 pubovaginal had a 2.3 percent?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Now, I understand -- didn't</p> <p>14 you tell me earlier you never hit the</p> <p>15 bladder with a pubovaginal sling?</p> <p>16 A. Twice.</p> <p>17 Q. Twice you did?</p> <p>18 A. In well over 2,000.</p> <p>19 Q. But, apparently, other folks</p> <p>20 have a much higher incidence of hitting</p> <p>21 the bladder doing a pubovaginal sling</p> <p>22 than you, correct?</p> <p>23 A. According to this, yeah.</p> <p>24 As I said, before I accept</p>	<p>1 say.</p> <p>2 MR. SNELL: Let's take a</p> <p>3 short break, because I do have to</p> <p>4 use the restroom.</p> <p>5 - - -</p> <p>6 (Whereupon, a brief recess</p> <p>7 was taken.)</p> <p>8 - - -</p> <p>9 BY MR. SNELL:</p> <p>10 Q. Doctor, in your report, you</p> <p>11 talk about chronic mesh pain syndrome.</p> <p>12 Is that a recognized</p> <p>13 diagnostic code that's used in billing</p> <p>14 and assessments?</p> <p>15 A. You know, I'm sorry, I don't</p> <p>16 know.</p> <p>17 Q. Do you do any transobturator</p> <p>18 type procedures in your practice?</p> <p>19 A. No, I don't.</p> <p>20 Q. Would you ever consider</p> <p>21 performing a transobturator autologous</p> <p>22 sling?</p> <p>23 A. No.</p> <p>24 Q. Why not?</p>
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<p>1 any of these things as valid, I would</p> <p>2 want to read the studies.</p> <p>3 Q. That was based on 14</p> <p>4 pubovaginal studies involving over a</p> <p>5 thousand patients, correct?</p> <p>6 A. Yes.</p> <p>7 Q. Your knowledge of the SGS</p> <p>8 and the way -- you're familiar with the</p> <p>9 SGS, and they've come out with systematic</p> <p>10 reviews over the years on different</p> <p>11 topics pertaining to female pelvic</p> <p>12 medicine?</p> <p>13 A. Yes.</p> <p>14 Q. And you found those reviews</p> <p>15 to be reliable?</p> <p>16 A. I don't know. I really</p> <p>17 haven't paid that much attention to it.</p> <p>18 But, you know, the data is</p> <p>19 only reliable as the methodology for the</p> <p>20 studies. And I said repeatedly that, in</p> <p>21 my judgment, the methodology for looking</p> <p>22 at these complications is seriously</p> <p>23 flawed and I'm not sure. And these</p> <p>24 are -- you know, I would just have to</p>	<p>1 A. I don't see any advantage to</p> <p>2 it. I mean, it's a -- I just don't see</p> <p>3 any advantage.</p> <p>4 Q. Are there risks of operating</p> <p>5 in the transobturator space that are</p> <p>6 unique or different than operating in the</p> <p>7 retropubic space?</p> <p>8 A. Sure. All the neuropathies</p> <p>9 and the thigh pains that we see.</p> <p>10 Q. Can dissecting through the</p> <p>11 obturator space cause neuropathies?</p> <p>12 A. If anything, it's possible.</p> <p>13 Q. If you were going to do a</p> <p>14 transobturator autologous sling, would</p> <p>15 you anticipate there being a risk of</p> <p>16 groin pain or thigh pain?</p> <p>17 A. It's totally hypothetical.</p> <p>18 I wouldn't do it.</p> <p>19 Q. But knowing the space and</p> <p>20 the area, the anatomy, would you</p> <p>21 anticipate that there would be a risk of</p> <p>22 groin and thigh pain?</p> <p>23 A. Well, only because of the</p> <p>24 experience of the transobturator mesh, to</p>

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<p>1 the extent that -- I mean, it's pretty 2 clear to me that the obturator nerve 3 doesn't have to be exactly where it's 4 supposed to be. 5 Again, it's a blind 6 procedure. 7 Q. Do you believe that case 8 reports are among the lowest form of 9 medical evidence? 10 A. Not for complications, I 11 don't. 12 Q. Why is that? 13 A. Because they exist. If one 14 person -- if the complications -- to a 15 certain extent, I think they are one of 16 the highest forms; either case reports or 17 case series of complications, because 18 there's no other way to accrue them. 19 Q. Case reports and case 20 series, though, don't tell you the 21 incidence or probability of the 22 complication, correct? 23 A. Correct. 24 Q. And, for example, in the</p>	<p>1 four U.S. tertiary referral centers? 2 A. I do. 3 Q. Let's mark that. 4 - - - 5 (Whereupon, Exhibit 6 Blaivas-21, Abbott Paper, was 7 marked for identification.) 8 - - - 9 BY MR. SNELL: 10 Q. This is one of the papers 11 you cite to in your report? 12 A. Right. 13 Q. And the problem with a paper 14 like this is it doesn't allow one to 15 calculate the incidence or probability 16 of a complication, correct? 17 A. Correct. 18 Well, I don't consider that 19 to be a problem. But what you said is 20 factually correct. 21 Q. This is, essentially, a 22 series of patients who reported 23 complications, and the paper reports on 24 how they were treated, correct?</p>
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<p>1 Abbott study that you cite to, that was a 2 case series of patients who had 3 complications, correct? 4 A. I need to see the paper 5 again. It's been a long time. 6 Q. You recall they went to 7 tertiary care center? 8 A. This is the one from three 9 groups, Cincinnati? 10 MS. FITZPATRICK: They'll 11 get it for you, if you don't 12 remember. 13 MR. SNELL: I'm looking for 14 it. 15 THE WITNESS: If I can't 16 answer a general question, I'll 17 tell you. 18 BY MR. SNELL: 19 Q. Do you recall the Abbott 20 study, though, was a paper that reported 21 on a series of patients who had reported 22 mesh complications -- 23 A. I do. 24 Q. -- who were evaluated at</p>	<p>1 A. Correct. 2 Q. In fact, I think if you turn 3 back to the second-to-last page, it says, 4 where they're talking about limitations, 5 besides the fact it was retrospective, it 6 says, Perhaps most importantly, there is 7 no denominator for the total number of 8 patients who underwent an SUI or POP 9 procedure. Thus, we can make no comments 10 about the rate at which such 11 complications occur. 12 You agree with that? 13 A. I do. 14 Q. And this looks at not only 15 the TVT sling mesh but the transvaginal 16 mesh as well, for prolapse, correct? 17 A. Yes. 18 Q. And you acknowledge that the 19 rates of potential complications with TVT 20 are lower than that with the transvaginal 21 prolapse mesh? 22 A. Yes. 23 Q. And what they state, if you 24 look at the preceding page, just -- where</p>

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<p>1 it's got Table 4, it says, Additionally, 2 those women with complications after 3 sling-only procedure were treated more 4 often with -- 5 A. I'm sorry, where are you? 6 Q. Let me just show you, that 7 way you can -- I don't want to lose time. 8 I'm kind of reading right there. 9 A. Okay. 10 Q. Are you with me? 11 A. Where? 12 Q. Additionally, those women -- 13 A. Yes. 14 Q. Tell me when you're there. 15 A. I'm there. 16 Q. Okay. This paper, they 17 reported that women with complications 18 after a sling-only procedure were treated 19 more often with medical treatment first 20 and rarely required surgical 21 re-intervention, correct? 22 A. That's what it says, yes. 23 Q. And that's consistent with 24 the literature, correct?</p>	<p>1 complications. We've seen it over and 2 over and over again. 3 So I just don't agree with 4 that conclusion. 5 Q. Can you give me an accurate 6 number as to the rate of the women who 7 are treated within the first year and 8 then have to have intervention later on 9 down the road? 10 A. A sizable number. I can't 11 give you the percent off the top of my 12 head. 13 Q. Why would you cite to this 14 paper, the Abbott paper, then, if you're 15 disagreeing with the things they say 16 about the TVT slings? 17 A. I didn't say I disagree with 18 the things they said. I think the 19 overall data -- there's lots of things in 20 here that I think are important. It 21 doesn't mean I have to agree with every 22 statement. 23 Q. So some of their findings 24 were actually inconsistent with your</p>
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<p>1 A. No, I'm not -- it's 2 consistent with the literature, but I 3 don't agree -- again, I'm familiar with 4 the methodology that came to those 5 conclusions and the follow-up is simply 6 too short to agree with their conclusion. 7 This is what the paper says. 8 It's not data, it's their comment. And I 9 would take issue with it. 10 Q. Well, their comment is based 11 on data because they did look at how 12 frequently the complication was treated 13 with medical intervention as opposed to 14 surgical intervention in the study, 15 right? 16 A. Yes, but the follow-up was 17 too short to have any meaningful -- to 18 come to this conclusion. 19 There are other papers that 20 I read recently, I'm sorry, I can't cite, 21 and my own experiences, that many 22 patients who have been treated medically 23 are okay for six months or a year or two 24 years and then go on to have</p>	<p>1 opinions, but you still cited to the 2 paper, right? 3 MS. FITZPATRICK: Objection. 4 Misstates the testimony. 5 THE WITNESS: I would say 6 probably every paper has things 7 you agree with and you disagree 8 with. You take the -- you know, 9 you take the good with the bad -- 10 not is the good with the bad. 11 I mean, you -- there are 12 some things that have good science 13 to them. I mean, for example, I 14 was looking for it and I can't 15 quite cite this, but in this 16 paper, there's data on what 17 percentage of patients went back 18 to their original doctor. And my 19 recollection -- my recollection is 20 that only about half of the 21 patients -- I could be wrong, I 22 could be off by 50 percent, but a 23 significant percentage of the 24 patients did not go back to the</p>

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<p>1 original doctor, probably never 2 even knew this happened. So data 3 like that is important. 4 And there were a number of 5 things that I did think were 6 important about -- about this 7 patient. I mean, for example, the 8 median number of surgeries per 9 patient was one. But 21 percent 10 of the patients required more 11 surgery for the same thing. So 12 one in -- so those kind of -- 13 See, whenever there's a 14 positive statement, something 15 happened, you can be confident 16 that it happened. But if -- if 17 someone doesn't -- if someone 18 doesn't report a complication, it 19 doesn't mean there wasn't one. 20 But if someone reports it, 21 it happened. And that's the way 22 we get our information about 23 complications. 24 BY MR. SNELL:</p>	<p>1 that. 2 Q. Well, when you see a patient 3 for a referral, or if you know who the 4 primary treating gynecologist or 5 urogynecologist is and you do a 6 procedure, don't you write that doctor 7 and say, here is what I did? 8 A. I ask the patient for their 9 permission. I mean, because a lot of -- 10 some of them don't want the doctor to 11 know, God knows. But I need their 12 permission to do that; unless the patient 13 was referred to me by the doctor. 14 But I can tell you, I can -- 15 I mean, the overwhelming majority of 16 patients that I see are not referred by 17 the operating doctor. And to a large 18 extent, the operating doctor doesn't know 19 about it. 20 And the reason I know is, 21 because I usually ask -- I always ask the 22 patient if it's okay to communicate with 23 their primary -- with the doctor that did 24 the surgery.</p>
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<p>1 Q. A couple of things I want to 2 follow up on. 3 First, you mentioned that 4 some of the patients didn't go back to 5 their doctors? 6 A. Yes. 7 Q. We know these are tertiary 8 care centers? 9 A. Yes. 10 Q. And you know -- do you know 11 what percent of the patients were 12 referred by their primary doctors to 13 their tertiary care center for treatment 14 of the mesh complications? 15 A. I think it's in the paper. 16 But no, I don't know. 17 Q. Do you know what percentage 18 of the tertiary centers actually 19 communicated back with the referring 20 doctors to tell them the outcomes and how 21 patients were doing? 22 A. I don't. But that's exactly 23 the kind of stuff that you want to know. 24 Because that's -- let me leave it at</p>	<p>1 Q. Are you aware of data to the 2 contrary, that shows that more than 50 3 percent of patients go back to their 4 primary doctors who did the implantation 5 of the mesh for treatment? 6 A. I don't know -- I know a 7 significant number don't. But I don't 8 know -- I don't know the data well enough 9 to answer that question. 10 Well, actually, I know that 11 at least a third -- I read recently in 12 one study -- 13 Q. Go ahead. I'm listening. 14 A. I know in one study that I 15 recently read, a third of the patients 16 never notified their operating surgeon. 17 Q. A third, you said? 18 A. Yes. 19 Q. In this study, the average 20 number of interventions was one, correct? 21 A. Yes. 22 Q. So more likely than not, 23 once the patient has an intervention, 24 according to this study, she will not</p>

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<p>1 need another one, correct?</p> <p>2 A. No. That's what I was</p> <p>3 saying before. I mean, we've seen many</p> <p>4 patients that have had -- had an</p> <p>5 intervention and are okay for a couple of</p> <p>6 years and then need another one.</p> <p>7 I mean, that's my practice.</p> <p>8 And I see that commonly.</p> <p>9 Q. I understand. I understand</p> <p>10 that that can occur.</p> <p>11 But I'm talking about</p> <p>12 probability.</p> <p>13 A. We specifically looked --</p> <p>14 was that a question? You did not ask a</p> <p>15 question yet, I'm sorry.</p> <p>16 Q. My question was focused on</p> <p>17 probability.</p> <p>18 I will give you that</p> <p>19 patients can go back for a second</p> <p>20 reoperation. I'm talking about</p> <p>21 probability and what the actual data</p> <p>22 showed.</p> <p>23 In this study -- let me see,</p> <p>24 I think it's reported in here. For the</p>	<p>1 patient will need just one surgery?</p> <p>2 A. No, that's correct, it's not</p> <p>3 clear to me.</p> <p>4 Q. Is it important to you to</p> <p>5 know whether or not a patient you're</p> <p>6 treating for mesh removal is involved in</p> <p>7 litigation?</p> <p>8 A. No, not really.</p> <p>9 Q. Have you evaluated the</p> <p>10 medical literature with regard to</p> <p>11 potential bias by financial gain to</p> <p>12 patients involved in litigation and how</p> <p>13 they report their symptoms to doctors?</p> <p>14 MS. FITZPATRICK: Objection.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. Are you aware if there is</p> <p>18 literature, though, on that topic?</p> <p>19 A. No.</p> <p>20 Q. Haven't you written in the</p> <p>21 past that patients involved in litigation</p> <p>22 have a financial incentive to make</p> <p>23 claims?</p> <p>24 MS. FITZPATRICK: Objection.</p>
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<p>1 sling cohort, less than half had to have</p> <p>2 a second surgery.</p> <p>3 Is that consistent with your</p> <p>4 recollection of this study?</p> <p>5 A. Yes. But the follow-up</p> <p>6 was -- the follow-up for all of these</p> <p>7 things is too short for there to be any</p> <p>8 meaningful conclusion about whether or</p> <p>9 not they needed another operation.</p> <p>10 Q. Well, based on the data,</p> <p>11 though, it was more likely than not that</p> <p>12 one surgery would suffice in this study</p> <p>13 for the sling patients?</p> <p>14 A. I just -- I just said what</p> <p>15 my opinion was.</p> <p>16 Q. In the sling procedure, it</p> <p>17 said 23 percent had more than one</p> <p>18 surgery. So to that -- that, to you,</p> <p>19 does not mean -- 23 percent of the women</p> <p>20 who had these tertiary care center</p> <p>21 treatments had to have more than one</p> <p>22 surgery.</p> <p>23 That does not mean, to you,</p> <p>24 that it's more likely than not that a</p>	<p>1 THE WITNESS: I haven't</p> <p>2 written that, no.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. You haven't?</p> <p>5 In your opinion, does the</p> <p>6 TVT adequately treat stress urinary</p> <p>7 incontinence?</p> <p>8 MS. FITZPATRICK: Objection.</p> <p>9 THE WITNESS: In terms of</p> <p>10 efficacy, yes.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. And in your opinion, I take</p> <p>13 it you believe that the pubovaginal sling</p> <p>14 also adequately treats stress</p> <p>15 incontinence?</p> <p>16 A. Yes.</p> <p>17 Q. Apparently, over lunch, or</p> <p>18 some time, you called someone to try to</p> <p>19 get information about why papers were</p> <p>20 left off of your review?</p> <p>21 A. I did.</p> <p>22 Q. Who did you call?</p> <p>23 A. My previous -- actually, one</p> <p>24 of the authors of the paper, I think it</p>

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<p>1 was Matt Benedon. But he's a previous 2 research coordinator. 3 Q. Where is he at now? 4 A. He's still in New York, but 5 he doesn't work for me anymore. 6 Q. And what did you ask Matt? 7 A. Why those weren't there. 8 Q. What did he say? 9 A. That we used -- if the same 10 author wrote a previous paper using the 11 same cohort of patients, he only included 12 the one with the latest -- our 13 methodology was to only include the one 14 the latest date. 15 So, for example, one of the 16 papers we didn't -- I forget who the 17 first author was, but the senior author 18 was Nilsson, we did not include the 19 five-year paper, we included the 20 seventeen-year paper. There was a series 21 of papers. 22 So there were three that -- 23 that was one. 24 The Serati, or whatever that</p>	<p>1 A. We may -- let me see the 2 paper. 3 MS. FITZPATRICK: This is my 4 copy of it. I don't know what 5 number it is. 6 BY MR. SNELL: 7 Q. You said one with Nilsson. 8 I think that's the one where Nilsson is 9 on. 10 A. Give me one second. 11 Q. Can I look over your 12 shoulder? I can't find mine in that big 13 stack. 14 Yes, this is Nilsson, okay. 15 A. You're correct about that. 16 But that's the explanation. They thought 17 when the computer -- you know, the way we 18 did it, it pulled it up as the same 19 author, and they thought it was the same 20 cohort. 21 Q. But it's clearly not, 22 correct? 23 A. It's clearly not, correct. 24 Q. And it should have been</p>
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<p>1 one was, the 2013 paper was -- the 2 five-year follow-up was published later 3 than the ten-year follow-up, because the 4 ten-year follow-up was just TVT -- 5 Q. Can I stop you right there? 6 A. Yes. 7 Q. First of all, the cohort of 8 patients in Nilsson's study that's been 9 reported out to 17 years, that I know you 10 cited, is not the same cohort of people 11 in the prospective randomized five-year 12 control trial; you and I know that, 13 right? 14 A. They're different -- no, 15 they are different papers, right. 16 Q. They are different cohorts 17 of patients, right? 18 A. Let me see the paper. Which 19 one are you talking about? 20 Q. I'll take these one by one. 21 The first one you mentioned 22 with Nilsson, that's the Laurikainen 23 five-year RCT. 24 Where is your paper at?</p>	<p>1 included, correct? 2 A. Yes, it should have. 3 Q. And Serati, those are two 4 different cohort of patients because the 5 ten-year study was TVT patients and the 6 five-year were TVT-O patients, correct? 7 A. And TVT. One of them had 8 TVT and TOT, I thought. 9 Well, let me see the two 10 papers, and we'll see. 11 MS. FITZPATRICK: I've only 12 got one. I think we only have one 13 marked, and I'm not sure what it 14 is. 15 BY MR. SNELL: 16 Q. Do you have it in front of 17 you there, Doctor? 18 A. I must. 19 MS. FITZPATRICK: Is it 20 Number 12? Here. That's the only 21 one we have. We don't have the 22 second one, I don't think, the 23 2013. 24 THE WITNESS: I need to see</p>

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<p>1 the other one, the one that --</p> <p>2 this is what year? I need to see</p> <p>3 the one that was printed -- what</p> <p>4 year is this?</p> <p>5 This is 2012. We need to</p> <p>6 see the one from 2014. The same</p> <p>7 author had a paper in 2014.</p> <p>8 MS. FITZPATRICK: 2013.</p> <p>9 THE WITNESS: 2013.</p> <p>10 BY MR. SNELL:</p> <p>11 Q. But that was a group of</p> <p>12 TVT-O patients that were only analyzed at</p> <p>13 five years?</p> <p>14 A. Can I just see it?</p> <p>15 Q. I don't have it, but we have</p> <p>16 it on the computer here.</p> <p>17 A. Let me see in the table --</p> <p>18 hold on.</p> <p>19 Let me just see in our</p> <p>20 table. I'll be able to tell just by</p> <p>21 looking in the table.</p> <p>22 Q. I think the simple thing is</p> <p>23 this. I think you should be able to</p> <p>24 agree with me that a ten-year group of</p>	<p>1 on. This doesn't change the</p> <p>2 conclusions one bit.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. I thought you said that</p> <p>5 there is less long-term ten-year data on</p> <p>6 TVT?</p> <p>7 A. Including this. I already</p> <p>8 went through the fact that the</p> <p>9 methodology to look at the kinds of</p> <p>10 complications that we saw is not</p> <p>11 sufficient. It didn't seek it out.</p> <p>12 I mean, it didn't have a</p> <p>13 way -- I mean, again, I agree that 8</p> <p>14 percent is a great loss to follow up.</p> <p>15 But the problem is, it's not so great --</p> <p>16 it's great for efficacy. But it's not so</p> <p>17 great looking for complication that</p> <p>18 occurs in 1 or 2 percent of patients.</p> <p>19 So if only one -- there's</p> <p>20 only one patient, one or two patients</p> <p>21 that had that complication, they were</p> <p>22 more likely to be in the</p> <p>23 loss-to-follow-up group according to --</p> <p>24 or -- they were very likely to be, I</p>
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<p>1 women who got TVT implanted is not the</p> <p>2 same group who had five-year follow-up</p> <p>3 after a TVT-O implanted?</p> <p>4 A. Of course. But --</p> <p>5 Q. In your paper, you cited to</p> <p>6 this five-year TVT-O paper, and I'll give</p> <p>7 you that, it's in there, but the ten-year</p> <p>8 TVT group was not in there?</p> <p>9 A. Just let me check one thing.</p> <p>10 That's correct. And that</p> <p>11 was -- that was just an error. But the</p> <p>12 error was because it was the same author</p> <p>13 with mesh slings. And our methodology</p> <p>14 said that if it was -- they mistakenly</p> <p>15 thought it was the same cohort.</p> <p>16 Q. Clearly, it's important to</p> <p>17 capture ten-year TVT studies that are out</p> <p>18 there in the published literature and</p> <p>19 journals like European Urology, correct?</p> <p>20 MS. FITZPATRICK: Objection.</p> <p>21 THE WITNESS: Not to -- not</p> <p>22 in a safety consideration for</p> <p>23 synthetic sling study that is</p> <p>24 already -- there's plenty of data</p>	<p>1 couldn't say that they were more likely</p> <p>2 to be.</p> <p>3 They are at least one-third</p> <p>4 more likely to be in that group because</p> <p>5 we know at least one-third of the</p> <p>6 patients don't go back to their original</p> <p>7 doctors.</p> <p>8 So that an 8 percent loss to</p> <p>9 follow up, although extraordinarily</p> <p>10 commendable for an efficacy study, is not</p> <p>11 so commendable to look for something that</p> <p>12 happens 1 or 2 percent of the time.</p> <p>13 Q. The problem with what you</p> <p>14 just said, though, Doctor, is when you</p> <p>15 said we know a third of the patients</p> <p>16 don't go back to their doctors, we know</p> <p>17 that in Serati, 92 percent of them went</p> <p>18 back to their doctors, right?</p> <p>19 MS. FITZPATRICK: Objection.</p> <p>20 THE WITNESS: That's right.</p> <p>21 But 8 percent did not.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. But 8 percent and a third is</p> <p>24 a big difference, isn't it?</p>

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<p>1 MS. FITZPATRICK: Objection.</p> <p>2 THE WITNESS: Well, no, no.</p> <p>3 I actually stand by what I said.</p> <p>4 I don't think I need to say it</p> <p>5 again.</p> <p>6 BY MR. SNELL:</p> <p>7 Q. So in Serati's paper, where</p> <p>8 only 8 percent didn't go back to the</p> <p>9 doctor, why are you telling me that we</p> <p>10 know a third of patients don't go back to</p> <p>11 their doctor?</p> <p>12 MS. FITZPATRICK: Objection.</p> <p>13 Mischaracterizes his testimony.</p> <p>14 THE WITNESS: The reason I</p> <p>15 said that is there's a chance that</p> <p>16 the -- let's say these -- I forget</p> <p>17 the numbers now, but these were,</p> <p>18 like, 60 patients or 70 patients.</p> <p>19 So 60 patients, if one -- we</p> <p>20 would not expect there to be more</p> <p>21 than one, say, erosion out of</p> <p>22 that. That would be -- you know,</p> <p>23 that would, or urethral</p> <p>24 obstruction that required -- say</p>	<p>1 BY MR. SNELL:</p> <p>2 Q. I'm really trying to</p> <p>3 understand your methodology and your</p> <p>4 statement there.</p> <p>5 MS. FITZPATRICK: Objection</p> <p>6 to the form of the question.</p> <p>7 THE WITNESS: I'll try to</p> <p>8 say it again.</p> <p>9 I didn't say they're more</p> <p>10 likely to be in that group. I</p> <p>11 didn't say that they are more</p> <p>12 likely to be in that group. It's</p> <p>13 just that I think that -- maybe I</p> <p>14 did say that. If I did, I</p> <p>15 misspoke.</p> <p>16 I said there's a chance that</p> <p>17 they could be in the group. And</p> <p>18 since the complications we're</p> <p>19 talking about are so uncommon,</p> <p>20 okay, I don't think it's fair to</p> <p>21 say that if a complication didn't</p> <p>22 occur in the 92 percent of the</p> <p>23 patients that were followed up,</p> <p>24 that, therefore, it never</p>
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<p>1 requiring surgery would be 1 or 2</p> <p>2 percent. Okay.</p> <p>3 So there only -- in that 8</p> <p>4 percent, the one patient could</p> <p>5 have been the one patient who had</p> <p>6 the complication, and that one</p> <p>7 patient, it would be more likely</p> <p>8 that that person would be in the</p> <p>9 loss-to-follow-up group than in</p> <p>10 the not loss-to-follow-up group.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. How is it that you can say</p> <p>13 that that one patient is more likely in</p> <p>14 the loss-to-follow-up group than the 92</p> <p>15 percent of the patients who did return?</p> <p>16 MS. FITZPATRICK: Objection.</p> <p>17 THE WITNESS: I already</p> <p>18 explained my rationale for that.</p> <p>19 BY MR. SNELL:</p> <p>20 Q. I don't understand it.</p> <p>21 It would seem to me that</p> <p>22 sheer statistical 92 percent probability</p> <p>23 that they would come back?</p> <p>24 MS. FITZPATRICK: Objection.</p>	<p>1 occurred. That's all I'm saying.</p> <p>2 BY MR. SNELL:</p> <p>3 Q. Okay. We can agree that in</p> <p>4 Serati's paper, where 92 percent of the</p> <p>5 patients did come back and they didn't</p> <p>6 report any de novo dyspareunia and they</p> <p>7 did not see any exposure, that's actually</p> <p>8 a good thing for those patients who came</p> <p>9 back and were able to be evaluated?</p> <p>10 A. I'm going to split it</p> <p>11 between the dyspareunia and the erosion.</p> <p>12 All the patients were</p> <p>13 examined, so I'll give you that.</p> <p>14 But the dyspareunia, if you</p> <p>15 don't ask about it and you don't know if</p> <p>16 the patient is sexually active, you can't</p> <p>17 make a comment about dyspareunia, in my</p> <p>18 judgment. If they say they have</p> <p>19 dyspareunia, you can make a comment. If</p> <p>20 you did not say specifically, do you have</p> <p>21 sex and does it hurt, I don't think you</p> <p>22 can say -- you can make a comment.</p> <p>23 Q. But when the authors report</p> <p>24 there was no de novo dyspareunia, that</p>

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<p>1 means they asked about it, they assessed 2 it, right?</p> <p>3 A. If that were the case, it 4 would be in the methods. And if it 5 wasn't -- if they asked about it and did 6 not put it in the methods, then it's 7 their fault for not putting it in the 8 methods. And if they didn't ask about 9 it, then they can't conclude it.</p> <p>10 And I don't even like 11 talking about this because I think it's 12 very good paper. I don't mean to malign 13 the authors at all. This is an excellent 14 paper, but just not with respect -- they 15 did the best they could with this stuff. 16 But it's not good enough to satisfy me 17 that if the patients don't complain of 18 pain, they don't have it.</p> <p>19 I haven't -- I made my 20 statement.</p> <p>21 Q. Regardless, that's a paper 22 that should have been in your review, 23 right?</p> <p>24 A. Yes.</p>	<p>1 data and we did use it for calculations. 2 It just didn't make -- it just didn't get 3 in that table.</p> <p>4 Q. So there is much more five 5 year long-term data in the literature 6 than what you put in that table, correct?</p> <p>7 A. Well, there are three.</p> <p>8 Q. Three that I showed you 9 today?</p> <p>10 A. Yes.</p> <p>11 Q. There could be 12 more?</p> <p>12 MS. FITZPATRICK: Objection. 13 THE WITNESS: I don't know. 14 But if there are, let's not 15 discuss them today.</p> <p>16 BY MR. SNELL: 17 Q. Is part of your methodology 18 based on case series?</p> <p>19 A. Yes.</p> <p>20 Q. Do you give more weight to 21 case series than randomized control 22 trials or systematic reviews?</p> <p>23 A. I give weight to anything 24 that documents a complication. I don't</p>
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<p>1 Q. And you were about to -- 2 were you about to give me some 3 justification for why the other paper 4 didn't show up in there?</p> <p>5 A. Which one was that?</p> <p>6 Q. Heinonen, 10.5 years, 7 follow-up, no long --</p> <p>8 A. Which one?</p> <p>9 Q. Heinonen, 10.5 years --</p> <p>10 A. I need to see it.</p> <p>11 MS. FITZPATRICK: This one. 12 BY MR. SNELL: 13 Q. No late tissue reaction 14 exposure, where they did vaginal 15 examinations with speculum?</p> <p>16 A. This just missed the table, 17 it's in the paper. This is referenced, 18 it's part of our data. We just -- it 19 didn't get in the table.</p> <p>20 Q. In your paper, you reported 21 there were only 11.</p> <p>22 That one obviously should 23 have been in there as well?</p> <p>24 A. Yeah. But we did use it as</p>	<p>1 give weight to someone that doesn't 2 comment on -- you know, on complications.</p> <p>3 So most of the studies, 4 many -- I would say -- I could say that 5 most of the studies don't even have 6 anything in their methodology to accrue 7 complications, other than -- than patient 8 reported.</p> <p>9 So if the patient says -- 10 said that it hurt, something hurts, they 11 would accept it. But they don't -- if 12 they don't prompt for it, they don't 13 check for it, I don't give that any 14 credence at all.</p> <p>15 Q. Nilsson, 17-year paper?</p> <p>16 A. Yes.</p> <p>17 Q. Are you critical of the loss 18 to follow up in that paper as being 19 something outside the norm for a 17-year 20 data set or is that within the norm of 21 what you would expect at 17 years?</p> <p>22 A. Again, the loss to follow 23 up, I think, was acceptable for that 24 period of time. But some of the stuff</p>

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<p>1 they could have -- you know, loss to 2 follow up Alzheimer's disease, that was 3 one of the categories. That does not 4 mean that the patient didn't have a mesh 5 erosion, it did not mean they didn't have 6 dyspareunia; it just means they have 7 Alzheimer's disease. 8 And the patients -- of 9 course the patients that died. But I 10 would have wanted to see them -- and they 11 did not prompt for the kinds of 12 complications that we're talking about. 13 Q. Did the majority of the mesh 14 complications occur in the first year? 15 A. In that paper. 16 Q. No, no. In general? 17 A. In general, yes. I would 18 say the majority of reported 19 complications occurred in the first year. 20 Q. Do you know who -- you know 21 Stuart Stanton? 22 A. Sure. 23 Q. He was one of the surgeons 24 who was highly involved in bringing about</p>	<p>1 duration? 2 A. I mean, it's understandable. 3 I mean, when you say "acceptable," 4 there's a difference between what's 5 practical and what's scientific -- it's 6 not scientifically acceptable. But 7 practically, of course, it's acceptable. 8 Q. When you say "practically 9 it's acceptable," you mean stuff happens? 10 A. It's the best you can do, 11 yeah. 12 MR. SNELL: Let's mark that. 13 - - - 14 (Whereupon, Exhibit 15 Blaivas-22, Stress Urinary 16 Incontinence AUA Monograph, was 17 marked for identification.) 18 - - - 19 BY MR. SNELL: 20 Q. Doctor, I've given you a 21 stress urinary incontinence AUA 22 monograph. 23 You're familiar with this 24 document?</p>
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<p>1 the Burch or at least reintroducing it, 2 correct? 3 A. Yes. Wait a minute. Sorry. 4 I'm not sure I know what you're talking 5 about with the Burch. 6 Q. He's over in England, 7 London? 8 A. I know exactly who he is. 9 But, I mean, what was -- I didn't get 10 your comment about the Burch. 11 Q. Let me withdraw my comment. 12 You know who Stuart Stanton 13 is? 14 A. Yes. 15 Q. A surgeon in London who has 16 published on the Burch colposuspension? 17 A. Yes. 18 Q. In a study where he looked 19 at the Burch ten to twenty-year 20 follow-up, the loss to follow up was 21 about 68 percent. 22 Is that an acceptable level 23 of loss to follow up, in your opinion, 24 for a study of ten to twenty years'</p>	<p>1 A. I am. 2 Q. Do you actually use a stress 3 urinary incontinence monograph with your 4 patients who have incontinence? 5 A. I do not. You mean -- no, I 6 don't. 7 Q. If you look at Page 10, 8 where they're talking about surgical 9 management, you see mesh and pelvic floor 10 surgery on the right? 11 A. Yes. 12 Q. Where they talk about the -- 13 they refer to the AUA's October 2013 14 position statement on the use of mesh, 15 correct? 16 A. Yes, they do. 17 Q. And a little further down 18 where they're talking about 19 complications, the AUA, they report that 20 prolonged pain occurs in 1 percent? 21 A. Yes. 22 Q. You agree with that? 23 A. No. 24 Sorry for laughing.</p>

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<p>1 Q. Well, that's very similar to</p> <p>2 the 1.4 percent you reported in your</p> <p>3 paper, correct, for retropubic slings, at</p> <p>4 least?</p> <p>5 A. That's based on the flawed</p> <p>6 literature we discussed. We said that we</p> <p>7 believe it's more like 4 percent, based</p> <p>8 on the analysis that I described before.</p> <p>9 Q. But I'm only focused on the</p> <p>10 retropubic TVT, not lumping in</p> <p>11 transobturator slings.</p> <p>12 That 1 percent reported in</p> <p>13 this AUA monograph is consistent with the</p> <p>14 1.4 percent you reported specifically for</p> <p>15 the TVT and retropubic slings in your</p> <p>16 paper, right?</p> <p>17 A. Yes.</p> <p>18 Q. And the vaginal exposure, 1</p> <p>19 to 2 percent, is also consistent with</p> <p>20 what was reported with regard to the</p> <p>21 retropubic TVT in your paper?</p> <p>22 A. Yes.</p> <p>23 Q. And the erosion into the</p> <p>24 urinary tract, less than .01 percent,</p>	<p>1 mesh. And this is the October 2013</p> <p>2 revised statement.</p> <p>3 Do you see that?</p> <p>4 A. Yes, I do.</p> <p>5 Q. AUA says, Extensive data</p> <p>6 exists to support the use of synthetic</p> <p>7 polypropylene mesh suburethral slings for</p> <p>8 the treatment of female SUI with minimal</p> <p>9 morbidity compared to alternative</p> <p>10 surgeries.</p> <p>11 Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. You agree with that part of</p> <p>14 the position statement?</p> <p>15 A. Do I agree what?</p> <p>16 Q. You agree with that part of</p> <p>17 the position statement from the AUA?</p> <p>18 A. I agree it says that. But,</p> <p>19 no, I don't agree with that. Again, I --</p> <p>20 no, I don't agree with that.</p> <p>21 Q. Advantages include shorter</p> <p>22 operative time, anesthetic need, reduced</p> <p>23 surgical pain, reduced hospitalization</p> <p>24 and reduced voiding dysfunction.</p>
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<p>1 that's consistent with what you found?</p> <p>2 A. No, it's not. We found</p> <p>3 about, I think it was .4 percent, just</p> <p>4 for the record, which is --</p> <p>5 Q. .4 percent for erosion in</p> <p>6 the bladder?</p> <p>7 A. This says bladder or</p> <p>8 urethra.</p> <p>9 Q. Erosion into the urethra,</p> <p>10 you would agree, is less than .01</p> <p>11 percent?</p> <p>12 A. Probably around that. It's</p> <p>13 uncommon.</p> <p>14 - - -</p> <p>15 (Whereupon, Exhibit</p> <p>16 Blaivas-23, American Urology</p> <p>17 Association Position Paper, was</p> <p>18 marked for identification.)</p> <p>19 - - -</p> <p>20 BY MR. SNELL:</p> <p>21 Q. Exhibit 23, this is the AUA</p> <p>22 position statement --</p> <p>23 A. Okay.</p> <p>24 Q. -- on the use of vaginal</p>	<p>1 I think we covered most of</p> <p>2 those before, except we didn't get into</p> <p>3 reduced surgical pain.</p> <p>4 You would agree there is</p> <p>5 reduced surgical pain with the TVT</p> <p>6 compared to --</p> <p>7 A. You mean perioperative?</p> <p>8 Yes.</p> <p>9 Q. Which is -- it's consistent</p> <p>10 with having to strip off the woman's</p> <p>11 tissue?</p> <p>12 A. Sure.</p> <p>13 Q. That can be very painful,</p> <p>14 correct?</p> <p>15 A. I mean, it's like -- I would</p> <p>16 say it's less so than most operations,</p> <p>17 because we don't go into the abdominal</p> <p>18 cavity.</p> <p>19 Q. And that would be a</p> <p>20 benefit --</p> <p>21 MR. SNELL: I'm sorry?</p> <p>22 MS. FITZPATRICK: It's about</p> <p>23 5:50, I want you to know.</p> <p>24 MR. SNELL: You have a hard</p>

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<p>1 stop?</p> <p>2 - - -</p> <p>3 (Whereupon, a discussion off</p> <p>4 the record occurred.)</p> <p>5 - - -</p> <p>6 MR. SNELL: I will put on</p> <p>7 objection on the record, because I</p> <p>8 would have liked to complete this</p> <p>9 deposition today. I will ask that</p> <p>10 there be obviously no</p> <p>11 communication between you and the</p> <p>12 witness, if we resume. And I'm</p> <p>13 not even sure if I'm willing to</p> <p>14 resume.</p> <p>15 MS. FITZPATRICK: Well, I'm</p> <p>16 going to have 15 minutes, so if</p> <p>17 you don't want to come back for</p> <p>18 it, we'll do a 15-minute follow-up</p> <p>19 by phone.</p> <p>20 MR. SNELL: Those things</p> <p>21 being said, you have a safe trip</p> <p>22 to your meeting, Doctor.</p> <p>23 THE WITNESS: Okay.</p> <p>24 - - -</p>	<p>1 CERTIFICATE</p> <p>2</p> <p>3</p> <p>4 I HEREBY CERTIFY that the</p> <p>5 witness was duly sworn by me and that the</p> <p>6 deposition is a true record of the</p> <p>7 testimony given by the witness.</p> <p>8</p> <p>9</p> <p>10</p> <p>11 Amanda Maslinsky-Miller</p> <p>12 Certified Realtime Reporter</p> <p>13 Dated: September 21, 2015</p> <p>14</p> <p>15</p> <p>16</p> <p>17 (The foregoing certification</p> <p>18 of this transcript does not apply to any</p> <p>19 reproduction of the same by any means,</p> <p>20 unless under the direct control and/or</p> <p>21 supervision of the certifying reporter.)</p> <p>22</p> <p>23</p> <p>24</p>
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<p>1 (Whereupon, Exhibit</p> <p>2 Blaivas-24, Expert Report of J.</p> <p>3 Blaivas, was marked for</p> <p>4 identification.)</p> <p>5 - - -</p> <p>6 (Parties agreed to mark the</p> <p>7 expert report as 24.)</p> <p>8 - - -</p> <p>9 (Whereupon, the deposition</p> <p>10 concluded at 5:49 p.m.)</p> <p>11 - - -</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it.</p> <p>10 You are signing same subject</p> <p>11 to the changes you have noted on the</p> <p>12 errata sheet, which will be attached to</p> <p>13 your deposition.</p> <p>14 It is imperative that you</p> <p>15 return the original errata sheet to the</p> <p>16 deposing attorney within thirty (30) days</p> <p>17 of receipt of the deposition transcript</p> <p>18 by you. If you fail to do so, the</p> <p>19 deposition transcript may be deemed to be</p> <p>20 accurate and may be used in court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<div style="text-align: center;"> <p>1 -----</p> <p> E R R A T A</p> <p>2 -----</p> <p>3 PAGE LINE CHANGE/REASON</p> </div> <div style="margin-top: 10px;"> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> </div>	<div style="text-align: center;"> <p>1 LAWYER'S NOTES</p> <p>2 PAGE LINE</p> </div> <div style="margin-top: 10px;"> <p>3 _____</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> </div>
<div style="text-align: right; padding-bottom: 10px;">Page 355</div> <div style="text-align: center; padding-bottom: 10px;"> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> </div> <div style="margin-top: 10px;"> <p>2 I, _____, do</p> <p>3 hereby certify that I have read the</p> <p>4 foregoing pages, 1 - 349, and that the</p> <p>5 same is a correct transcription of the</p> <p>6 answers given by me to the questions</p> <p>7 therein propounded, except for the</p> <p>8 corrections or changes in form or</p> <p>9 substance, if any, noted in the attached</p> <p>10 Errata Sheet.</p> <p>11 _____</p> <p>12 JERRY BLAIVAS, M.D., DATE</p> <p>13 Subscribed and sworn</p> <p>14 to before me this</p> <p>15 _____ day of _____, 20____.</p> <p>16 My commission expires: _____</p> <p>17 _____</p> <p>18 Notary Public</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> </div>	

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., :Master File No.
PELVIC REPAIR SYSTEM :2:12-MD-0237
PRODUCTS LIABILITY :
LITIGATION :MDL No. 2327

THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN
THE CASES LISTED BELOW :U.S. DISTRICT JUDGE

Mullins, et al. V.	2:12-cv-02952
Ethicon, Inc., et al.	
Sprout, et al. V.	2:12-cv-07924
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Ethicon, Inc., et al.	
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SEPTEMBER 24, 2015
CONTINUED DEPOSITION OF JERRY G. BLAIVAS, M.D.

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<p>1 CAPTION CONTINUED:</p> <p>2 Mullens, et al. V. 2:13-cv-16564</p> <p>3 Ethicon, Inc., et al.</p> <p>4 Shears, et al. V. 2:13-cv-17012</p> <p>5 Ethicon, Inc., et al.</p> <p>6 Javins, et al. V. 2:13-cv-18479</p> <p>7 Ethicon, Inc., et al.</p> <p>8 Barr, et al. V. 2:13-cv-22606</p> <p>9 Ethicon, Inc., et al.</p> <p>10 Lambert v. Ethicon, 2:13-cv-24393</p> <p>11 Inc., et al.</p> <p>12 Cook v. Ethicon, Inc. 2:13-cv-29260</p> <p>13 Stevens v. Ethicon, 2:13-cv-29918</p> <p>14 Inc., et al.</p> <p>15 Harmon v. Ethicon, Inc. 2:13-cv-31818</p> <p>16 Snodgrass v. Ethicon, 2:13-cv-31881</p> <p>17 Inc., et al.</p> <p>18 Miller v. Ethicon, Inc. 2:13-cv-32627</p> <p>19 Matney, et al. V. 2:14-cv-09195</p> <p>20 Ethicon, Inc., et al.</p> <p>21 Jones, et al. V. 2:14-cv-09517</p> <p>22 Ethicon, Inc., et al.</p> <p>23 Humbert v. Ethicon, 2:14-cv-10640</p> <p>24 Inc., et al.</p> <p>25 Gillum, et al. V. 2:14-cv-12756</p> <p>26 Ethicon, Inc., et al.</p> <p>27 Whisner, et al. V. 2:14-cv-13023</p> <p>28 Ethicon, Inc., et al.</p> <p>29 Tomblin v. Ethicon, 2:14-cv-14664</p> <p>30 Inc., et al.</p> <p>31 Schepleng v. Ethicon, 2:14-cv-16061</p> <p>32 Inc., et al.</p> <p>33 Tyler, et al. V. 2:14-cv-19110</p> <p>34 Ethicon, Inc., et al.</p> <p>35 Kelly, et al. V. 2:14-cv-22079</p> <p>36 Ethicon, Inc., et al.</p> <p>37 Lundell v. Ethicon, 2:14-cv-24911</p> <p>38 Inc., et al.</p> <p>39 Cheshire, et al. V. 2:14-cv-24999</p> <p>40 Ethicon, Inc., et al.</p> <p>41 Burgoyne, et al., V. 2:14-cv-28620</p> <p>42 Ethicon, Inc., et al.</p> <p>43 Bennett, et al., V. 2:14-cv-29624</p> <p>44 Ethicon, Inc., et al.</p>	<p>1 APPEARANCES:</p> <p>2</p> <p>3 MOTLEY RICE LLC</p> <p>4 BY: FIDELMA L. FITZPATRICK, ESQ.</p> <p>5 321 South Main Street, 2nd Floor</p> <p>6 Providence, Rhode Island 02903</p> <p>7 (401) 457-7728</p> <p>8 Ffitzpatrick@motleyrice.com</p> <p>9 Counsel for the Plaintiffs</p> <p>10</p> <p>11 BUTLER SNOW, LLP</p> <p>12 BY: NILS B. (BURT) SNELL, ESQ.</p> <p>13 500 Office Center Drive, Suite 400</p> <p>14 Fort Washington, Pennsylvania 19034</p> <p>15 (267) 513-1885</p> <p>16 Burt.snell@butlersnow.com</p> <p>17 Counsel for the Defendant</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
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<p>1 Continued transcript of JERRY G. BLAIVAS,</p> <p>2 M.D., called for Oral Examination in the</p> <p>3 above-captioned matter, said deposition taken by and</p> <p>4 before SILVIA P. WAGE, a Certified Shorthand</p> <p>5 Reporter, Certified Realtime Reporter, Registered</p> <p>6 Professional Reporter, and Notary Public for the</p> <p>7 States of New Jersey, New York, Pennsylvania and</p> <p>8 Delaware, at the offices of URO CENTER, 445 East</p> <p>9 77th Street, New York, New York, on Thursday,</p> <p>10 September 24, 2015, commencing at 2:48 p.m.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 INDEX</p> <p>2 WITNESS: JERRY G. BLAIVAS, M.D. PAGE</p> <p>3 CONTINUED EXAMINATION BY MR. SNELL 363/415</p> <p>4 /428</p> <p>5 EXAMINATION MS. FITZPATRICK 386/426</p> <p>6</p> <p>7 EXHIBITS</p> <p>8 EXHIBIT NO. DESCRIPTION PAGE</p> <p>9 Blaivas 25 Long-term outcomes of TVT and 367</p> <p>10 IVS operations for treatment</p> <p>11 of female stress urinary</p> <p>12 incontinence: Monofilament vs.</p> <p>13 Multifilament polypropylene</p> <p>14 tape authored by Jens</p> <p>15 Christian Prien-Larsen and</p> <p>16 Lars Hemmingsen</p> <p>17 Blaivas 26 Long-term Results of the 373</p> <p>18 Tension-free Vaginal Tape</p> <p>19 Procedure in an Unselected</p> <p>20 Group: A 7-year Follow-up</p> <p>21 Study authored by Andreas</p> <p>22 Reich, Frauke Kohorst, Rolf</p> <p>23 Krenenberg and Felix Flock</p> <p>24 Blaivas 27 Long-term efficacy of 380</p> <p>25 tension-free vaginal tape in</p> <p>26 the management of stress</p> <p>27 urinary incontinence in women:</p> <p>28 Efficacy at 5- and 7-year</p> <p>29 follow-up by A. Lissipis, P.</p> <p>30 Baskas and G. Creatsas</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p> <p>35</p> <p>36</p> <p>37</p> <p>38</p> <p>39</p> <p>40</p> <p>41</p> <p>42</p> <p>43</p> <p>44</p>

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Golkow Technologies, Inc. - 1.877.370.DEPS

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<p>1 - - -</p> <p>2 DEPOSITION SUPPORT INDEX</p> <p>3 - - -</p> <p>4</p> <p>5 Direction to Witness Not to Answer</p> <p>6 Page Line Page Line Page Line Page Line</p> <p>7 None</p> <p>8</p> <p>9</p> <p>10 Request for Production of Documents</p> <p>11 Page Line Page Line Page Line Page Line</p> <p>12 None</p> <p>13</p> <p>14</p> <p>15 Stipulations</p> <p>16 Page Line Page Line Page Line Page Line</p> <p>17 None</p> <p>18</p> <p>19</p> <p>20 Motion to Strike</p> <p>21 Page Line Page Line Page Line Page Line</p> <p>22 371 5 375 11 375 16 376 14</p> <p>23 385 9 394 4 406 12 407 6</p> <p>24 425 22</p>	<p>1 your CV that you're involved with some companies.</p> <p>2 A. Yes.</p> <p>3 Q. What types of development or products</p> <p>4 are you working on?</p> <p>5 A. My overwhelming effort is a</p> <p>6 company that I founded called SomeTelligence and</p> <p>7 we're working on -- we're working on a new method of</p> <p>8 facilitating communications between doctors and</p> <p>9 patients that allows most of the history to be</p> <p>10 obtained for the patient and doctor by the patient</p> <p>11 on the cell phone and then that gets translated into</p> <p>12 an outcome score that serves as the first step in</p> <p>13 diagnosis and then it's useful for following</p> <p>14 patients for treatment and clinical research.</p> <p>15 Q. Have you invented anything?</p> <p>16 A. Yeah. Yes.</p> <p>17 Q. What?</p> <p>18 A. I invented a device for measuring</p> <p>19 urethral mobility -- simultaneously measuring</p> <p>20 urethral mobility and leak point pressure as an</p> <p>21 objective measure of the severity of incontinence --</p> <p>22 Q. Did you sell --</p> <p>23 A. -- stress incontinence.</p> <p>24 Q. Did you sell that device to anyone?</p>
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<p>1 JERRY G. BLAIVAS, M.D.,</p> <p>2 Uro Center, 445 East 77th Street, New York,</p> <p>3 New York, after having been duly sworn, was</p> <p>4 examined and testified as follows:</p> <p>5 CONTINUED EXAMINATION BY MR. SNELL:</p> <p>6 Q. Dr. Blaivas, I'm going to be brief.</p> <p>7 I'm Burt Snell. We're just picking up on your</p> <p>8 deposition.</p> <p>9 Have you done any work since the time of</p> <p>10 your deposition I took from you on Friday, looking</p> <p>11 at any materials, talked to Plaintiffs' counsel?</p> <p>12 A. I haven't talked to Plaintiffs'</p> <p>13 counsel. I did some work -- I mean, I did some more</p> <p>14 reading of stuff that was already -- I just reread</p> <p>15 some of the stuff that was already on the reliance</p> <p>16 list.</p> <p>17 Q. Let me ask you this.</p> <p>18 A. Excuse me just one second. I'm just</p> <p>19 trying to turn my phone off and I can't seem to do</p> <p>20 it while we're talking.</p> <p>21 MR. SNELL: Let's go off the record.</p> <p>22 (There is a discussion off the record.)</p> <p>23 MR. SNELL: Okay. Back on.</p> <p>24 Q. I saw from your website and I think</p>	<p>1 A. Yeah. It was actually -- it was</p> <p>2 produced for a short time by a company called -- I'm</p> <p>3 trying to remember the name. I'm drawing a blank on</p> <p>4 the name of the company. But they were then</p> <p>5 subsequently sold by AMS and they never did anything</p> <p>6 with it. It just sort of got buried.</p> <p>7 Influence was the company. Influence was</p> <p>8 the name of the company.</p> <p>9 Q. Were you paid anything for your</p> <p>10 invention?</p> <p>11 A. I had stock options, yeah.</p> <p>12 Q. Did you find that reasonable, that</p> <p>13 you were paid for your invention via stock options?</p> <p>14 A. Sure.</p> <p>15 Q. Would you describe yourself as</p> <p>16 entrepreneurial?</p> <p>17 A. Not really. I'm not motivated by</p> <p>18 business and financial things, you know. So I don't</p> <p>19 consider myself "entrepreneurial."</p> <p>20 Q. Let me pick up partly where we left</p> <p>21 off. We were talking about the AUA guidelines and</p> <p>22 the monograph and then the updated position</p> <p>23 statement and we had marked that.</p> <p>24 You're aware that there are position</p>

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<p>1 statements and guidelines by AUG, SUFU, IUGA and</p> <p>2 other entities involved in women's public health?</p> <p>3 A. I am.</p> <p>4 Q. And some of those guidelines speak to</p> <p>5 the utility of the TVT retropubic device?</p> <p>6 A. I'm aware of that, yes.</p> <p>7 Q. Is it that you disagree at all with</p> <p>8 those statements and guidelines with regard to TVT's</p> <p>9 utility?</p> <p>10 MS. FITZPATRICK: Objection.</p> <p>11 A. I don't understand what you mean by</p> <p>12 "utility."</p> <p>13 Q. The usefulness of the device.</p> <p>14 MS. FITZPATRICK: Objection.</p> <p>15 A. I disagree with the safety aspect of</p> <p>16 it. I don't disagree with the efficacy aspect.</p> <p>17 Q. Okay. And you remember at the last</p> <p>18 deposition I showed you some longer-term TVT studies</p> <p>19 that hadn't been considered by you in your review?</p> <p>20 A. Yes. But it turns out that some of</p> <p>21 them had been. They just weren't included in the</p> <p>22 table but, yes.</p> <p>23 MR. SNELL: Give me some exhibits.</p> <p>24 Q. I want to show you some others. I</p>	<p>1 electronic copy of it.</p> <p>2 THE WITNESS: I, actually, think</p> <p>3 there is one on my desk.</p> <p>4 MS. FITZPATRICK: Maybe it's</p> <p>5 conveniently --</p> <p>6 MR. SNELL: Well, let's take a break</p> <p>7 and go off the record.</p> <p>8 (Recess taken 2:53 to 2:54 p.m.)</p> <p>9 Q. So, Dr. Blaivas, I've given you my</p> <p>10 copy of your review article that we had previously</p> <p>11 marked as Exhibit 4, correct?</p> <p>12 A. Correct.</p> <p>13 Q. And, if you look at Table 1, it has</p> <p>14 the five-year plus studies.</p> <p>15 This paper that I've handed you by</p> <p>16 Prien-Larsen was not included, correct?</p> <p>17 A. It wasn't included in the table. But</p> <p>18 I don't know if it was included in our analysis</p> <p>19 because this table related to effectiveness studies</p> <p>20 and we may have had different criteria for including</p> <p>21 those in the table.</p> <p>22 Q. Okay. And what you'll see in this</p> <p>23 paper is they have looked at not only effectiveness</p> <p>24 but safety of TVT compared to IVS in this paper,</p>
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<p>1 want to do these quickly because I don't have a lot</p> <p>2 of time.</p> <p>3 (Deposition Exhibit Blaivas 25, Long-term</p> <p>4 outcomes of TVT and IVS operations for treatment of</p> <p>5 female stress urinary incontinence: Monofilament vs.</p> <p>6 Multifilament polypropylene tape authored by Jens</p> <p>7 Christian Prien-Larsen and Lars Hemmingsen, was</p> <p>8 marked for identification.)</p> <p>9 Q. First one, Exhibit 25, Doctor, the</p> <p>10 6.5-year study in the International Urogynecology</p> <p>11 Journal.</p> <p>12 You're familiar with that journal, right?</p> <p>13 A. I am.</p> <p>14 Q. This study by Prien-Larsen was not</p> <p>15 included in your table in your review.</p> <p>16 Have you reviewed this paper?</p> <p>17 A. Study by whom?</p> <p>18 Q. Prien-Larsen. I may not be</p> <p>19 pronouncing the name right.</p> <p>20 A. Oh, okay.</p> <p>21 MS. FITZPATRICK: Do we have a copy</p> <p>22 of his "Nature" article, too, so he can look at it?</p> <p>23 MR. SNELL: Do you have a copy of it?</p> <p>24 MS. FITZPATRICK: I've got an</p>	<p>1 right?</p> <p>2 A. Let me...</p> <p>3 Q. If you look in the result section.</p> <p>4 A. No, I want to look at something else</p> <p>5 first in the methods section.</p> <p>6 MR. SNELL: Then go off the record.</p> <p>7 (Recess taken 2:55 to 2:56 p.m.)</p> <p>8 MR. SNELL: Back on the record.</p> <p>9 Q. This study we're looking at by</p> <p>10 Prien-Larsen, L-a-r-s-e-n, looked at not only</p> <p>11 efficacy but also safety, correct?</p> <p>12 A. I don't see anything about safety.</p> <p>13 Q. Okay.</p> <p>14 A. There's one -- go on.</p> <p>15 Q. I'll show you.</p> <p>16 So, for efficacy, they compared TVT to IVS</p> <p>17 and, for example, at the last follow-up there was</p> <p>18 94 percent objective cure with TVT and 80 percent</p> <p>19 with IVS with TVT being statistically significantly</p> <p>20 better, correct?</p> <p>21 A. If that's what it says. I don't --</p> <p>22 Q. Can I direct your attention to the</p> <p>23 front, just so you and I are on the same page?</p> <p>24 A. Uh-huh.</p>

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<p>1 Q. I would not misrepresent some data to</p> <p>2 you.</p> <p>3 A. No.</p> <p>4 Q. Is that okay?</p> <p>5 A. Yeah, I agree.</p> <p>6 Q. A P-value of less than .03 is</p> <p>7 statistically significant, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And there was a significant</p> <p>10 decline in subjective cure that was seen in the IVS</p> <p>11 cohort, correct?</p> <p>12 A. Correct.</p> <p>13 Q. Vaginal erosions were tracked in the</p> <p>14 study as well, right?</p> <p>15 A. Yes. Well, it -- it wasn't tracked.</p> <p>16 It says that it was defined as -- it doesn't</p> <p>17 actually say how they determined that.</p> <p>18 Q. You see they say that vaginal</p> <p>19 erosions were found in 11.8 percent of women in the</p> <p>20 IVS group and none in the TVT group, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And under the results follow-up,</p> <p>23 you'll see the median follow-up in this study was</p> <p>24 78 months, correct?</p>	<p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And the IVS mesh is not a Type 1</p> <p>4 macroporous monofilament polypropylene mesh,</p> <p>5 correct?</p> <p>6 A. The which?</p> <p>7 Q. The IVS mesh is not a Type 1</p> <p>8 monofilament --</p> <p>9 A. No, it's not.</p> <p>10 (There is a discussion off the record.)</p> <p>11 A. Excuse me. It's not. It's not.</p> <p>12 Q. Just so we have a clear record now,</p> <p>13 the IVS where there was over an 11 percent rate of</p> <p>14 vaginal exposure seen is not a Type 1 macroporous</p> <p>15 monofilament polypropylene mesh like TVT retropubic,</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. Alright. And do you have any idea</p> <p>19 why this paper wasn't cited in your review?</p> <p>20 MS. FITZPATRICK: Objection.</p> <p>21 A. I assume it was likely an exclusion</p> <p>22 criteria based on our very detailed methodology. I</p> <p>23 don't know.</p> <p>24 Q. You don't know that as you sit here</p>
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<p>1 A. Let me just see. I just want to</p> <p>2 check one thing out.</p> <p>3 Yeah, I'm not finding the numbers lost to</p> <p>4 follow-up.</p> <p>5 MR. SNELL: [MOTION] Move to strike.</p> <p>6 Q. You see my question was, Doctor --</p> <p>7 and I have very limited time -- the median length of</p> <p>8 follow-up in the TVT group was 78 months, correct?</p> <p>9 A. Yes.</p> <p>10 Q. Alright. And you'll see, actually,</p> <p>11 all of Page 706, they have a whole section on the</p> <p>12 treatment of these vaginal erosions.</p> <p>13 A. Yes.</p> <p>14 Q. And that flows all the way over to</p> <p>15 the next page, Table 5, where they identify all the</p> <p>16 different presenting symptoms in women with vaginal</p> <p>17 erosions, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Including how treatment was necessary</p> <p>20 or not in the women who had the vaginal erosions,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. And, just to reiterate, and all of</p> <p>24 these patients with erosions were in the IVS group,</p>	<p>1 today?</p> <p>2 A. No.</p> <p>3 (Deposition Exhibit Blaivas 26, Long-term</p> <p>4 Results of the Tension-free Vaginal Tape Procedure</p> <p>5 in an Unselected Group: A 7-year Follow-up Study</p> <p>6 authored by Andreas Reich, Frauke Kohorst, Rolf</p> <p>7 Krelenberg and Felix Flock, was marked for</p> <p>8 identification.)</p> <p>9 Q. Exhibit 26, you see this is long-term</p> <p>10 results of the TVT procedure in an unselected group</p> <p>11 of patients, seven-year follow-up, correct?</p> <p>12 A. Let me look at it. I mean, I'm</p> <p>13 seeing this for the first time.</p> <p>14 Q. Fair enough. Let me ask you this.</p> <p>15 This is, actually, published in the Journal</p> <p>16 of Urology, correct?</p> <p>17 A. Yes.</p> <p>18 Q. That's a journal you get, right?</p> <p>19 A. Yes, I get it.</p> <p>20 Q. Is that the journal to my left here</p> <p>21 on the bookcase?</p> <p>22 A. It is.</p> <p>23 Q. Okay. Fair enough.</p> <p>24 MR. SNELL: Go off the record.</p>

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<p>1 Q. Can you look at it.</p> <p>2 A. Okay.</p> <p>3 (There is a discussion off the record.)</p> <p>4 Q. So this was a study where the median</p> <p>5 follow-up time was 102 months, correct?</p> <p>6 A. Yes.</p> <p>7 Q. So that's what about nine years?</p> <p>8 A. Uh-huh.</p> <p>9 Q. Is that a yes?</p> <p>10 A. Yes.</p> <p>11 Q. And they looked at cure rates as well</p> <p>12 as complications, correct?</p> <p>13 A. I'll have to look at that and see.</p> <p>14 Q. In the results section, it says the</p> <p>15 objective cure rate was 89.8 percent and then they</p> <p>16 go on and talk about subjective cures and</p> <p>17 improvements. Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. This study, also, stated no late</p> <p>20 onset ever.</p> <p>21 So events of the surgery were found in the</p> <p>22 results section, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And, if we look at your Table 1, this</p>	<p>1 MR. SNELL: Allot her time to her.</p> <p>2 Go ahead.</p> <p>3 MS. FITZPATRICK: This is a</p> <p>4 misrepresentation by Mr. Snell of this article.</p> <p>5 And, quite frankly, at this point, it's an</p> <p>6 intentional misrepresentation.</p> <p>7 This article is cited for the safety</p> <p>8 propositions that Dr. Blaivas has in this article.</p> <p>9 The fact that it is not in Table 1 should be the</p> <p>10 question --</p> <p>11 MR. SNELL: Move to strike --</p> <p>12 MS. FITZPATRICK: -- not that it is</p> <p>13 not cited in the article.</p> <p>14 MR. SNELL: [MOTION] move to strike</p> <p>15 attorney testimony.</p> <p>16 MS. FITZPATRICK: Objection to the</p> <p>17 motion to strike.</p> <p>18 Q. Dr. Blaivas --</p> <p>19 MS. FITZPATRICK: And objection to</p> <p>20 attorney misrepresentation of something that I hope,</p> <p>21 certainly, doesn't see the light of day in court</p> <p>22 pleadings.</p> <p>23 MR. SNELL: You know, if you want to</p> <p>24 get in the chair, get in the chair. I can depose</p>
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<p>1 long-term TVT study was not included either,</p> <p>2 correct?</p> <p>3 MS. FITZPATRICK: Objection. This is</p> <p>4 misrepresenting completely what's in this article.</p> <p>5 A. It's --</p> <p>6 MS. FITZPATRICK: I'm objecting to</p> <p>7 that question.</p> <p>8 MR. SNELL: That's fine.</p> <p>9 MS. FITZPATRICK: Because --</p> <p>10 MR. SNELL: No, no.</p> <p>11 [MOTION] Move to strike attorney comment.</p> <p>12 You have a form.</p> <p>13 MS. FITZPATRICK: I'm not going to</p> <p>14 move to strike it. This is complete</p> <p>15 misrepresentation.</p> <p>16 MR. SNELL: [MOTION] Move to strike.</p> <p>17 MS. FITZPATRICK: I'm going to put my</p> <p>18 objection on the record.</p> <p>19 MR. SNELL: That's fine. Then just</p> <p>20 say your objection, form. You're wasting my time.</p> <p>21 I have limited time. Quit burning my time with your</p> <p>22 talking.</p> <p>23 MS. FITZPATRICK: This is a</p> <p>24 misrepresentation.</p>	<p>1 you.</p> <p>2 MS. FITZPATRICK: Sure. I'm happy,</p> <p>3 go right ahead.</p> <p>4 Q. Dr. Blaivas --</p> <p>5 MS. FITZPATRICK: -- after me.</p> <p>6 MR. SNELL: I'm sure.</p> <p>7 Q. So back to what I read to you, right.</p> <p>8 The results say, no late onset adverse effects of</p> <p>9 the surgery were found, correct?</p> <p>10 A. Yes, that's what it says.</p> <p>11 Q. This study was not referenced in your</p> <p>12 Table 1 of long-term TVT studies, correct?</p> <p>13 MS. FITZPATRICK: Objection. Table 1</p> <p>14 is effectiveness and what you're referring to is</p> <p>15 safety. Stop misrepresenting, Burt.</p> <p>16 MR. SNELL: Did you just hear me say</p> <p>17 what the objective cure rate? This does --</p> <p>18 Q. Doctor --</p> <p>19 MS. FITZPATRICK: Did you just -- can</p> <p>20 you read back his question?</p> <p>21 Q. Doctor, look, let's make sure that</p> <p>22 we're one same page.</p> <p>23 MR. SNELL: You're wasting my time.</p> <p>24 MS. FITZPATRICK: Burt, you're</p>

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<p>1 misrepresenting.</p> <p>2 Q. Doctor, this is -- I withdraw my</p> <p>3 question.</p> <p>4 Did this study assess efficacy of the TVT?</p> <p>5 A. It is --</p> <p>6 MS. FITZPATRICK: Objection.</p> <p>7 A. It is efficacy, yes.</p> <p>8 Q. And this study is not in Table 1 of</p> <p>9 your review, correct?</p> <p>10 A. That is correct.</p> <p>11 Q. Fair enough.</p> <p>12 Now, if we look at -- you know what, can I</p> <p>13 see...</p> <p>14 A. Are you looking for this?</p> <p>15 Q. I just want to make sure I didn't say</p> <p>16 something.</p> <p>17 So it's not in Table 1, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And this study published in Urology</p> <p>20 -- is that a well-regarded journal by you?</p> <p>21 A. It is.</p> <p>22 Q. (Continuing.) Found no tape exposures</p> <p>23 or tape extrusions, correct?</p> <p>24 A. That's what they said in the article,</p>	<p>1 A. -- Urology. I think -- I wouldn't</p> <p>2 want to single out the Journal of Urology. I think</p> <p>3 that when it comes to results, I think -- excuse me.</p> <p>4 When it is comes to complications, I think they're</p> <p>5 all poor.</p> <p>6 Q. But you don't have any firsthand</p> <p>7 knowledge about what the authors did with regard to</p> <p>8 their assessment of dyspareunia or chronic pain?</p> <p>9 A. Well, of course not. That's supposed</p> <p>10 to be in the methods section.</p> <p>11 Q. I'm just saying.</p> <p>12 So you don't have firsthand personal</p> <p>13 knowledge that these authors did not assess</p> <p>14 dyspareunia or chronic pain?</p> <p>15 MS. FITZPATRICK: Objection.</p> <p>16 A. That's right. It did not.</p> <p>17 MR. SNELL: Next study is Lipsis.</p> <p>18 Let's mark this as Exhibit 27.</p> <p>19 (Deposition Exhibit Blaivas 27, Long-term</p> <p>20 efficacy of tension-free vaginal tape in the</p> <p>21 management of stress urinary incontinence in women:</p> <p>22 Efficacy at 5- and 7-year follow-up by A. Lipsis, P.</p> <p>23 Baskas and G. Creatsas, was marked for</p> <p>24 identification.)</p>
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<p>1 right.</p> <p>2 Q. They also said that at the point of</p> <p>3 follow-up 29 women were sexually active, correct?</p> <p>4 A. I'm sorry?</p> <p>5 Q. At the state of follow-up, 29 women</p> <p>6 were sexually active? I'm right about --</p> <p>7 A. Out of 108, yes.</p> <p>8 Q. Yes. And no woman suffered under</p> <p>9 dyspareunia, correct?</p> <p>10 A. It says that, but there is no methods</p> <p>11 -- there's no method to say how they determined</p> <p>12 that.</p> <p>13 Q. And they also state no further late</p> <p>14 adverse effects such as chronic pain or recurrent</p> <p>15 lower urinary tract infection were found, correct?</p> <p>16 A. Correct. But, again, that's not in</p> <p>17 the method. So I don't know how they can conclude</p> <p>18 it in their results.</p> <p>19 Q. Does the Journal of Urology have a</p> <p>20 poor peer review process?</p> <p>21 A. I think so. I think they -- yes, I</p> <p>22 think it does. This isn't the Journal of Urology.</p> <p>23 This is --</p> <p>24 Q. Urology.</p>	<p>1 Q. And looking back at the paper that we</p> <p>2 just referenced, Doctor, by Reich in Urology, do you</p> <p>3 have any idea why that was not included in Table 1?</p> <p>4 A. I already said, we had inclusion and</p> <p>5 exclusion criteria, No. 1. No. 2, because it's not</p> <p>6 in the table doesn't mean it isn't in our</p> <p>7 references, in the nearly 400 references. So I have</p> <p>8 to cross-check to see whether it was included or</p> <p>9 not.</p> <p>10 Q. As you sit here, you don't know why</p> <p>11 it wasn't included in Table 1?</p> <p>12 A. I don't know if it wasn't included.</p> <p>13 That's what I said.</p> <p>14 Q. Okay. What exhibit is that, Doc, 20?</p> <p>15 A. Twenty-seven.</p> <p>16 Q. Twenty-seven.</p> <p>17 Exhibit 27 is a paper with seven-year</p> <p>18 follow-up in TVT by Dr. Lipis, L-i-p-i-s, and some</p> <p>19 others. And I just want to check and we can check</p> <p>20 together.</p> <p>21 A. Yes.</p> <p>22 (There is a discussion off the record.)</p> <p>23 Q. And this was a paper that wasn't</p> <p>24 referenced in Table 1 of your review, correct?</p>

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<p>1 A. That's correct.</p> <p>2 Q. Okay. And if we look at this paper</p> <p>3 -- let me ask you.</p> <p>4 As you sit here, do you know why this paper</p> <p>5 was not referenced?</p> <p>6 A. No. The same answer I gave for the</p> <p>7 other ones. We'd have to see if it met our</p> <p>8 inclusion and/or exclusion criteria.</p> <p>9 Q. It did report on efficacy, right, if</p> <p>10 we look at Table 3, they report on both objective</p> <p>11 and subjective cures?</p> <p>12 A. I'm sorry? I didn't understand the</p> <p>13 question.</p> <p>14 Q. This paper, seven-year follow-up by</p> <p>15 Dr. Lipis and others, did assess efficacy of TVT --</p> <p>16 A. Yes.</p> <p>17 Q. -- in both five and seven years,</p> <p>18 correct?</p> <p>19 A. Correct.</p> <p>20 Q. And those data are in Tables 2 and 3,</p> <p>21 correct?</p> <p>22 A. Yes, yes.</p> <p>23 Q. Three being the seven years.</p> <p>24 A. Yes.</p>	<p>1 saying that that didn't occur?</p> <p>2 A. No, I'm not saying it didn't occur.</p> <p>3 What I am saying is that in order to determine</p> <p>4 whether or not someone has a complication or whether</p> <p>5 all patients have a complication, you have to have a</p> <p>6 methodology like asking a whole bunch of questions,</p> <p>7 for example, about complications or giving them a</p> <p>8 questionnaire to fill out and only by doing that can</p> <p>9 you determine what the denominator is.</p> <p>10 Q. And you don't know the methodology by</p> <p>11 which they did that in this case?</p> <p>12 A. No. I would expect to see it in the</p> <p>13 paper.</p> <p>14 Q. And they note that the rest of the</p> <p>15 patients had no evidence of tape erosion at the</p> <p>16 seven-year follow-up, correct?</p> <p>17 A. Right.</p> <p>18 Q. So these are -- this is three</p> <p>19 different studies we've looked at that weren't</p> <p>20 included in Table 1, correct, of your review?</p> <p>21 A. They weren't included in Table 1 for</p> <p>22 efficacy, correct.</p> <p>23 Q. You don't know why they weren't</p> <p>24 included, right?</p>
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<p>1 Q. And they, also, reported on</p> <p>2 complications as well, correct? If you look at the</p> <p>3 bottom of Page 1510, right column, they said that</p> <p>4 they had one case of the TVT tape erosion.</p> <p>5 A. Again, I'd have to look at the</p> <p>6 methods to see if there's any method that -- I'm</p> <p>7 looking at it quickly -- for detecting it. And I</p> <p>8 don't see anything. I mean, I looked quickly, but I</p> <p>9 don't see any methodology to allow us to understand</p> <p>10 how they came to the conclusion who had a</p> <p>11 complication and who didn't.</p> <p>12 Q. Well, when you do a vaginal exam, if</p> <p>13 you see a mesh exposure, you document it, right?</p> <p>14 MS. FITZPATRICK: Objection.</p> <p>15 A. If the patient -- yes, you do. But</p> <p>16 if the patient doesn't complain of any symptoms, you</p> <p>17 may do a very cursory exam or they can have many</p> <p>18 other complications that wouldn't be apparent on</p> <p>19 examination.</p> <p>20 Q. Well, whatever methodology they use,</p> <p>21 they reported that they found an exposure and they</p> <p>22 actually treat it by incising the sling, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you're not saying that -- are you</p>	<p>1 A. I would have to check the inclusion</p> <p>2 and exclusion criteria to see why they...</p> <p>3 Q. And -- fair enough.</p> <p>4 And none of these three additional studies</p> <p>5 reported late-term dyspareunia or tape exposure or</p> <p>6 erosion, correct?</p> <p>7 A. Nor did they have methodology to</p> <p>8 assess it, except for a pelvic exam.</p> <p>9 MR. SNELL: [MOTION] Move to strike.</p> <p>10 Q. Can you answer my question?</p> <p>11 MS. FITZPATRICK: Objection, the</p> <p>12 answer will stand. It's been asked and answered.</p> <p>13 Let's move on.</p> <p>14 MR. SNELL: No.</p> <p>15 Q. I want a yes or no --</p> <p>16 MS. FITZPATRICK: No.</p> <p>17 Q. -- then you can put your caveats in.</p> <p>18 MS. FITZPATRICK: You answer whatever</p> <p>19 way you have to to give a full and complete answer.</p> <p>20 It doesn't have to be a yes or no.</p> <p>21 THE WITNESS: I believe I did.</p> <p>22 MR. SNELL: Read it back.</p> <p>23 THE WITNESS: What's my answer?</p> <p>24 MR. SNELL: Read it back.</p>

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<p>1 (Whereupon, the answer is read back as</p> <p>2 follows:</p> <p>3 "Answer: Nor did they have methodology to</p> <p>4 assess it, except for a pelvic exam.")</p> <p>5 A. And that's my answer. If you want me</p> <p>6 to say, no, I can say, no, nor --</p> <p>7 Q. That's fine.</p> <p>8 A. -- did any of them have methodology</p> <p>9 to answer the question.</p> <p>10 Q. Yes, that's what I'm looking for, a</p> <p>11 responsive answer. And I'm more than happy to --</p> <p>12 MS. FITZPATRICK: Objection to the</p> <p>13 attorney comment.</p> <p>14 Q. I'm more than happy for you to give</p> <p>15 your caveat or whatever else. I'm not trying to</p> <p>16 stop you from doing that.</p> <p>17 This judge in this litigation has said a</p> <p>18 witness will be responsive, but they can give their</p> <p>19 caveat or whatever. So I'm giving you that. I'd</p> <p>20 just like an answer. And I thank you.</p> <p>21 MS. FITZPATRICK: You can answer any</p> <p>22 way you need to answer.</p> <p>23 MR. SNELL: Pass the witness.</p> <p>24 EXAMINATION BY MS. FITZPATRICK:</p>	<p>1 Q. Okay. And, as part of your education</p> <p>2 and training and experience as a urologic surgeon,</p> <p>3 you send specimens to pathology for review, correct?</p> <p>4 A. I do.</p> <p>5 Q. And that includes explanted</p> <p>6 transvaginal mesh that you remove from your</p> <p>7 patients, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And that's a removal that is done by</p> <p>10 you as a physician and not in connection with</p> <p>11 litigation, correct?</p> <p>12 MR. SNELL: Objection, lacks</p> <p>13 foundation and is leading.</p> <p>14 Go ahead.</p> <p>15 A. Yes.</p> <p>16 Q. And you regularly rely on pathology</p> <p>17 reports generated by pathologists in connection with</p> <p>18 your work as a urologist, correct?</p> <p>19 A. I do.</p> <p>20 Q. Okay. Do you have training and</p> <p>21 experience as a urologic surgeon relating to</p> <p>22 pathology -- strike that.</p> <p>23 Do you have training and experience as a</p> <p>24 urologic surgeon relating pathology reports to</p>
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<p>1 Q. Dr. Blaivas, I just have a few</p> <p>2 questions for you now.</p> <p>3 You testified that you're not a pathologist,</p> <p>4 correct?</p> <p>5 A. Correct.</p> <p>6 Q. Now, does that mean that you don't</p> <p>7 perform any pathology analysis in human tissue,</p> <p>8 correct?</p> <p>9 MR. SNELL: Objection, leading.</p> <p>10 A. I don't perform them, no, correct.</p> <p>11 Q. Do you as a physician order pathology</p> <p>12 review by pathologists on samples that you have</p> <p>13 removed from patients?</p> <p>14 A. I do.</p> <p>15 Q. And you just don't personally perform</p> <p>16 the analysis on explanted transvaginal mesh,</p> <p>17 correct?</p> <p>18 A. To a certain -- part of it I,</p> <p>19 actually, do because I exam it and part of the</p> <p>20 pathologic exam is to touch and feel it after it</p> <p>21 comes out. And I do do that in every case and I</p> <p>22 communicate that to the pathologist. But I'm sad to</p> <p>23 say they don't always keep -- include it in their</p> <p>24 report.</p>	<p>1 clinical complications in women?</p> <p>2 MR. SNELL: Objection, vague.</p> <p>3 Go ahead.</p> <p>4 A. I do.</p> <p>5 Q. And have you relied on this</p> <p>6 experience in connection with your report in this</p> <p>7 case?</p> <p>8 MR. SNELL: Objection, leading, lacks</p> <p>9 foundation, lacks methodology.</p> <p>10 Go ahead.</p> <p>11 A. I do.</p> <p>12 Q. Have you relied --</p> <p>13 MS. FITZPATRICK: Burt, go back to</p> <p>14 law school if you think that's leading.</p> <p>15 Q. Have you relied on your experience in</p> <p>16 this regard in connection with your report in this</p> <p>17 case, Dr. Blaivas?</p> <p>18 MR. SNELL: Same objections.</p> <p>19 A. I do but with an explanation. I very</p> <p>20 frequently, in fact, almost routinely question the</p> <p>21 pathologist about the pathology reports because they</p> <p>22 routinely don't do all of the things that I think</p> <p>23 should be done as part. So I often, you know,</p> <p>24 discuss it with them and sometimes ask them to not</p>

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<p>1 -- well, to give me a revised report based on things 2 that they didn't include in the original report. I 3 don't ask them to change, you know, their findings. 4 But not infrequently -- for example, many times they 5 don't even look at the tissue under the microscope. 6 And so the report will just come back, you know, tan 7 tissue without any microscopic diagnosis. So, when 8 that happens, I'll ask them if they would look at it 9 under the microscope and render their opinion about 10 that. 11 Q. Okay. In addition to your experience 12 in treating patients and reviewing their pathology 13 reports, as you've just described, are you also 14 familiar with medical and scientific literature 15 concerning pathology examination of explanted 16 transvaginal meshes? 17 A. Yes. 18 MR. SNELL: Leading. 19 Go ahead. 20 Q. And do you -- have you authored any 21 peer review articles that deal with pathology of 22 explanted transvaginal meshes? 23 A. I have. 24 Q. And when was that published?</p>	<p>1 A. Because it's part of what I do. 2 MS. FITZPATRICK: Okay. We're going 3 to take the objections and they're going to count 4 towards whatever time he has left. So, to the 5 extent that someone is going to object to why not as 6 a leading question, that is nothing more than 7 harassing and a complete abuse of the system. 8 MR. SNELL: No, it's not. My 9 original objection stood. You asked a follow-up one 10 and it's only natural that I re-assert it. 11 MS. FITZPATRICK: No, it's not. 12 MR. SNELL: Go ahead. 13 A. I have forgotten the question. 14 Q. Why don't you have to be a 15 pathologist or pathology expert to offer the 16 opinions that you have offered in this case? 17 MR. SNELL: Same objection, 18 foundation also. 19 A. Because my opinions are based on -- 20 they're simply based on pathology and the patient's 21 clinical course. I mean, I don't know how to 22 explain it in more detail than that. 23 Q. And is that something you routinely 24 do as a physician in treatment of women who had</p>
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<p>1 A. Well, it's the nature of the review 2 article that we alluded to before in 2015. And we 3 had an abstract and it was published -- myself and 4 Dr. Yacoub had an abstract published in 2014 in the 5 ICS, in Your Urology or in Uro Dynamics that we have 6 not completed the manuscript on that yet. 7 Q. And have you also authored peer 8 review articles that deal with the correlation 9 between clinical complications and pathology review 10 of explanted transvaginal meshes? 11 MR. SNELL: Objection, leading. 12 A. Yes. 13 Q. And are those the same articles that 14 you just mentioned? 15 A. They are. 16 Q. Okay. Do you need to be a 17 pathologist or a pathology expert to offer the 18 opinions that you have offered in this case? 19 A. Of -- 20 MR. SNELL: Objection, lacks 21 foundation -- hold on -- lacks foundation, leading. 22 A. Of course not. 23 Q. Why not? 24 MR. SNELL: Same objections.</p>	<p>1 pelvic mesh implants? 2 A. Absolutely. 3 Q. Now, you were also asked whether you 4 were an infectious disease specialist. Do you 5 recall that? 6 A. I do. 7 Q. Do you believe that you need to be an 8 infectious disease specialist to offer the opinions 9 that you have offered in this case? 10 MR. SNELL: Objection. 11 A. No, I do not. 12 Q. Why not? 13 A. Because infectious disease 14 specialists for practical purpose is never or almost 15 never see the kind of infections that we see related 16 to this. I see much more myself than any single 17 infectious disease doctor would see. 18 Q. And do you regularly work -- 19 MR. SNELL: I'm going to move -- 20 Q. -- to develop -- 21 (There is a discussion off the record.) 22 Q. Do you regularly work with women who 23 have developed infections secondary to the presence 24 of mesh, transvaginal polypropylene mesh, in this</p>

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<p>1 office?</p> <p>2 A. I --</p> <p>3 MR. SNELL: Hold on.</p> <p>4 [MOTION] Objection. I'm going to move to</p> <p>5 strike the last answer as totally speculative.</p> <p>6 Go ahead.</p> <p>7 Q. And have you treated those women?</p> <p>8 A. I'm sorry. I forgot the question</p> <p>9 now, again.</p> <p>10 Q. That's exactly what he's trying to</p> <p>11 do, Dr. Blaivas. So just pay attention to me and</p> <p>12 not to Mr. Snell, who is trying to throw you off</p> <p>13 your game here.</p> <p>14 In fact, in your training, education and</p> <p>15 experience as a urologic surgeon, do you regularly</p> <p>16 work with women who have developed infections</p> <p>17 secondary to the presence of mesh, polypropylene</p> <p>18 transvaginal mesh, in the office?</p> <p>19 MR. SNELL: Objection, lacks</p> <p>20 foundation.</p> <p>21 A. I do.</p> <p>22 Q. And have you treated those women?</p> <p>23 A. I have.</p> <p>24 Q. And have you managed their clinical</p>	<p>1 Were you referring to the TVT device, the</p> <p>2 TVT mesh and the trocars, the entire kit, when you</p> <p>3 were answering Mr. Snell's questions concerning</p> <p>4 implanting polypropylene mesh made by Ethicon?</p> <p>5 A. No, I was not.</p> <p>6 Q. Okay. And when is the last time you,</p> <p>7 actually, implanted any kind of polypropylene mesh</p> <p>8 made by Ethicon?</p> <p>9 A. You know, I've been asked this a</p> <p>10 number of times before and I gave my best estimate</p> <p>11 as in the mid 200s and I -- but I don't have any</p> <p>12 specific recollection.</p> <p>13 Q. Is it safe to say it's been about ten</p> <p>14 years?</p> <p>15 A. Yes.</p> <p>16 MR. SNELL: Objection, objection,</p> <p>17 vague.</p> <p>18 Q. Now, when you were --</p> <p>19 MR. SNELL: The witness just answered</p> <p>20 he doesn't know. It's speculation.</p> <p>21 Q. When you were referring to the slings</p> <p>22 that Mr. Snell kept referring to, you weren't</p> <p>23 referring to the TVT made by Ethicon, correct?</p> <p>24 MR. SNELL: Objection --</p>
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<p>1 complications?</p> <p>2 A. I have.</p> <p>3 Q. Does that include women who have been</p> <p>4 implanted with the TVT device?</p> <p>5 A. It has.</p> <p>6 Q. And when we were discussing pathology</p> <p>7 before, have you as a urologist who actually treats</p> <p>8 women look at the clinical complications of women</p> <p>9 who have a TVT device that has been explanted and</p> <p>10 related that to the pathology that you have received</p> <p>11 and report on?</p> <p>12 A. Yes, I have.</p> <p>13 Q. Okay. Now, you were also asked a few</p> <p>14 different questions about the warnings that you give</p> <p>15 patients when you implant polypropylene mesh made by</p> <p>16 Ethicon, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And Mr. Snell liked to use the term</p> <p>19 "sling" when he was asking you those questions. Do</p> <p>20 you recall that at all?</p> <p>21 MR. SNELL: Objection, misstates.</p> <p>22 Go ahead.</p> <p>23 A. I do.</p> <p>24 Q. And I want to clarify.</p>	<p>1 A. Right.</p> <p>2 MR. SNELL: -- misstates testimony.</p> <p>3 Q. Were you referring to any other sling</p> <p>4 kit that was made by Ethicon?</p> <p>5 A. No.</p> <p>6 Q. Were you referring to the TVT-O</p> <p>7 device that was made by Ethicon?</p> <p>8 A. No.</p> <p>9 Q. Were you referring to the Secure</p> <p>10 device that was made by Ethicon?</p> <p>11 A. No.</p> <p>12 Q. Were you referring to the TVT Abbrevio</p> <p>13 device that was made by Ethicon?</p> <p>14 A. No.</p> <p>15 Q. Do you believe that there is a</p> <p>16 different risk profile for the hand-cut mesh that</p> <p>17 you implanted more than a decade ago and the TVT</p> <p>18 Ethicon device that you've offered your expert</p> <p>19 opinion on in this case?</p> <p>20 MR. SNELL: Objection, beyond the</p> <p>21 scope.</p> <p>22 A. I do.</p> <p>23 Q. And do those require different</p> <p>24 surgical techniques?</p>

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<p>1 A. Yes.</p> <p>2 Q. Okay. Now, you were also asked a</p> <p>3 number of questions by Mr. Snell about the</p> <p>4 methodology for selecting articles in your report.</p> <p>5 Do you recall that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. In fact, we've heard a lot about it</p> <p>8 today. I want to ask you, specifically, something</p> <p>9 else.</p> <p>10 What was the methodology that you used in</p> <p>11 developing the opinions that you hold in your expert</p> <p>12 report that was produced in this case as opposed to</p> <p>13 the "Nature" article?</p> <p>14 A. The methodology --</p> <p>15 MR. SNELL: Objection, asked and</p> <p>16 answered.</p> <p>17 Go ahead.</p> <p>18 A. The methodology was -- first, my own</p> <p>19 personal experience with mesh, with mesh</p> <p>20 complications and with my firsthand knowledge of</p> <p>21 what my peers and the medical community at large</p> <p>22 that I interact with, what their opinions were and</p> <p>23 what they knew about the potential of mesh to cause</p> <p>24 complications and what they knew about the science</p>	<p>1 only there -- we only --</p> <p>2 Q. Can you take a look at the table</p> <p>3 again --</p> <p>4 MR. SNELL: Don't interrupt the</p> <p>5 witness.</p> <p>6 (There is a discussion off the record.)</p> <p>7 THE WITNESS: May I?</p> <p>8 MR. SNELL: Of course. Oh, I'm</p> <p>9 sorry.</p> <p>10 A. Yes, efficacy.</p> <p>11 Q. Okay.</p> <p>12 A. Isn't that what -- I'm sorry. I</p> <p>13 thought that's what I said.</p> <p>14 Q. That's okay.</p> <p>15 A. Yeah.</p> <p>16 Q. Now, in the literature review that</p> <p>17 you have performed for your expert report that</p> <p>18 you've offered here, did you include more articles</p> <p>19 that are referenced in your "Nature" article?</p> <p>20 MR. SNELL: Objection, lacks</p> <p>21 foundation.</p> <p>22 THE WITNESS: I'm sorry, can you read</p> <p>23 that back.</p> <p>24 (Whereupon, the question is read back as</p>
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<p>1 behind the theories that led to the use of mesh and</p> <p>2 their knowledge of the complications that had</p> <p>3 occurred in the past and were occurring during the</p> <p>4 present, whenever that was.</p> <p>5 So the first part of my answer is my own</p> <p>6 personal experience with all of these things. The</p> <p>7 second part is my review of the medical literature</p> <p>8 and tempered with a third part is my rather unique</p> <p>9 awareness of the medical literature because I was</p> <p>10 editor and chief for so many years of the major</p> <p>11 journal that dealt with these kinds of things. And</p> <p>12 I was also either on the editorial board or a</p> <p>13 reviewer for the other medical journals that dealt</p> <p>14 with this. So I had a perspective of all of the</p> <p>15 quality of the studies that were submitted for peer</p> <p>16 review and the methodology and I think it gave me a</p> <p>17 unique perspective on understanding the differences</p> <p>18 between the methodology that they use for</p> <p>19 complications versus the methodology they use for</p> <p>20 safety -- excuse me, for efficacy.</p> <p>21 Q. And, in fact, Table 1 that Mr. Snell</p> <p>22 asked you about in your "Nature" article, does that</p> <p>23 concern safety or does that concern efficacy?</p> <p>24 A. That concerns safety. And it was</p>	<p>1 follows:</p> <p>2 "Question: Now, in the literature review</p> <p>3 that you have performed for your expert report that</p> <p>4 you've offered here, did you include more articles</p> <p>5 that are referenced in your 'Nature' article?")</p> <p>6 MR. SNELL: Same objection.</p> <p>7 Q. That are referenced in your "Nature"</p> <p>8 article.</p> <p>9 A. I'm sorry, for the literature -- I'm</p> <p>10 sorry, I don't understand.</p> <p>11 Q. Let me try again, if you're not</p> <p>12 understanding.</p> <p>13 You have cited certain articles in your</p> <p>14 "Nature" article, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And I think it numbers somewhere in</p> <p>17 the 300s; is that about right?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And you, also, have provided a</p> <p>20 reliance list in this case in connection with your</p> <p>21 expert report, correct?</p> <p>22 A. Correct.</p> <p>23 Q. Do you know whether it included more</p> <p>24 articles than you cited in your "Nature" article?</p>

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<p>1 A. I think it included less.</p> <p>2 Q. And your reliance list itself -- do</p> <p>3 you have your expert report in front of you?</p> <p>4 A. I do not.</p> <p>5 MS. FITZPATRICK: Do you have a copy</p> <p>6 of the exhibit?</p> <p>7 MR. SNELL: No, I don't have that</p> <p>8 one.</p> <p>9 A. It's on my desk someplace.</p> <p>10 Q. We'll wait.</p> <p>11 (There is a discussion off the record.)</p> <p>12 Q. Well, let me ask you this, Doctor,</p> <p>13 just to cut through it.</p> <p>14 You provided a reliance list in connection</p> <p>15 with the articles that you reviewed in this report,</p> <p>16 correct?</p> <p>17 A. I did.</p> <p>18 Q. And is that an accurate</p> <p>19 representation of the number of articles that you</p> <p>20 have reviewed specific to your report in this TVT</p> <p>21 case?</p> <p>22 MR. SNELL: Objection, lacks</p> <p>23 foundation.</p> <p>24 A. Yes, it was -- is.</p>	<p>1 in your opinion in the literature to base the</p> <p>2 opinions that you've offered here on the safety and</p> <p>3 efficacy of the pubovaginal sling?</p> <p>4 MR. SNELL: Objection, vague. The</p> <p>5 witness has already testified.</p> <p>6 THE WITNESS: I'm sorry, read that</p> <p>7 back again.</p> <p>8 (Whereupon, the question is read back as</p> <p>9 follows:</p> <p>10 "Question: Is there sufficient evidence in</p> <p>11 your opinion in the literature to base the opinions</p> <p>12 that you've offered here on the safety and efficacy</p> <p>13 of the pubovaginal sling?")</p> <p>14 MR. SNELL: Objection, vague,</p> <p>15 overbroad.</p> <p>16 Go ahead.</p> <p>17 A. Okay. For the safety -- excuse me.</p> <p>18 For the efficacy, yes, and -- but my opinion</p> <p>19 for safety is based not only on the medical</p> <p>20 literature, which I've already said I think when it</p> <p>21 comes to safety is poor, but my review of what's not</p> <p>22 in the literature. So I suppose in a sense that's a</p> <p>23 review of the literature. So I'm going to say, yes,</p> <p>24 it is based on the medical literature.</p>
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<p>1 Q. Okay. And that was something that</p> <p>2 you personally reviewed and you personally approved</p> <p>3 prior to submitting it --</p> <p>4 A. Yes.</p> <p>5 Q. -- correct?</p> <p>6 And the articles that Mr. Snell has provided</p> <p>7 to you that he says are not on Table 1 of your</p> <p>8 "Nature" article, if those are included in your</p> <p>9 reliance list for the report that you offered in</p> <p>10 this case, would that be accurate to say that you</p> <p>11 have looked at those articles and considered them in</p> <p>12 connection with these opinions?</p> <p>13 MR. SNELL: Objection, requires</p> <p>14 speculation.</p> <p>15 A. Yes, it would.</p> <p>16 Q. Okay. Now, you also talked about the</p> <p>17 quality of literature on pubovaginal slings. Do you</p> <p>18 recall that?</p> <p>19 A. I do.</p> <p>20 Q. And I believe you said that the</p> <p>21 quality of that literature was "poor." Do you</p> <p>22 remember saying that?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Is there sufficient evidence</p>	<p>1 Q. Okay. Do you rely on anything else</p> <p>2 besides the published literature concerning your</p> <p>3 opinions on the safety and efficacy of the</p> <p>4 pubovaginal sling as set forth in your report?</p> <p>5 MR. SNELL: Objection, vague, asked</p> <p>6 and answered.</p> <p>7 A. Very very much so. And, in</p> <p>8 particular, for the last 20 years I've been running</p> <p>9 -- I've been either co-chairman or chairman or</p> <p>10 faculty member of courses that where in -- in which</p> <p>11 we always have sessions on complications. And we</p> <p>12 have whole sessions on complications of mesh slings.</p> <p>13 There's always, you know, half a day or, at least,</p> <p>14 an hour or two on mesh sling complications. We</p> <p>15 don't have -- this is even going back 25 years ago.</p> <p>16 We never had -- we never had such discussions of</p> <p>17 complications for autologous slings.</p> <p>18 And, again, Burch's just weren't done that</p> <p>19 much in the environment that I was in. It would be</p> <p>20 restricted to autologous slings. There just wasn't</p> <p>21 concern about it. The complications from autologous</p> <p>22 slings where the sling was too tight or not and</p> <p>23 caused obstruction, which could be relatively easily</p> <p>24 fixed by cutting the sling, or it caused de novo</p>

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<p>1 overactive bladder symptoms. But there were never 2 whole sections of seminars devoted to pelvic pain or 3 pain after slings. It just didn't exist. So -- and 4 it doesn't exist in the literature other than in a 5 few, in my judgment, poorly done studies. So all 6 that led me to believe that complications after mesh 7 slings are serious and serious problems that occur 8 often enough to capture the attention of both 9 academics and doctors in practice. Whereas 10 complications from autologous slings were pretty 11 much limited to those two complications that I said. 12 MR. SNELL: [MOTION] I'm going to 13 move to strike as nonresponsive. Also, move to 14 strike speculative, speculative testimony about 15 there was no concern of others -- no concern by 16 others. I'm just making my record. 17 MS. FITZPATRICK: Would you also just 18 put on the record why you believe you can move to 19 strike a deposition answer, Burt? Can you give us 20 the chapter and verse? 21 MR. SNELL: Because the witness 22 should answer a question responsively whether I 23 asked it or you asked it. 24 MS. FITZPATRICK: He did answer</p>	<p>1 that misstates my questioning. 2 A. I don't remember if that's the only 3 thing he asked me about. 4 Q. Did he primarily ask you about what 5 was and what was not included in Table 1, which is 6 the table that concerns efficacy, and not safety? 7 MR. SNELL: I'm going to object. 8 That misstates my questioning. 9 A. I do remember that being a main 10 thrust, yes. 11 Q. So let's talk a little bit about some 12 of those. For example, Mr. Snell asked you today 13 whether an article called, "The Long-Term Outcomes 14 of TVT and IVS Operations for Treatment of Female 15 Stress Urinary Incontinence: Monofilament Versus 16 Multifilament Polypropylene Tape" -- do you recall 17 that? 18 A. I do. 19 Q. And he asked you whether that had 20 been included in Table 1 -- it's, actually, 21 Exhibit 25 -- that had been included in Table 1 22 concerning efficacy, correct? 23 A. Correct. 24 Q. What he didn't ask you, which I think</p>
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<p>1 responsively. 2 So I object to Mr. Snell's meaningless 3 motion to strike. 4 Q. Let's move onto a little bit of what 5 Mr. Snell -- what I like to call the smoke and 6 mirrors of his deposition practice here. 7 MR. SNELL: [MOTION] I move to strike 8 attorney comment. That's not even a proper 9 question. 10 Q. The article that you drafted in 11 "Nature," can you read the title of that into the 12 record, please. 13 A. "Safety Considerations for Synthetic 14 Sling Surgery." 15 Q. And is it fair to say the primary 16 thrust of the article that you published with your 17 colleagues for "Nature" dealt with safety issues 18 concerning the polypropylene midurethral sling like 19 the TVT? 20 A. Yes. 21 Q. Okay. And Mr. Snell only asked you 22 about a single table, that is, Table 1, in that 23 article, correct? 24 MR. SNELL: Objection. Actually,</p>	<p>1 is more pertinent is, did you cite this in Footnote 2 212 of your article concerning the safety and rely 3 on this concerning safety conclusions you reached 4 about the midurethral polypropylene study? 5 MR. SNELL: Objection, leading, 6 argumentative. 7 A. Yes, I did. 8 Q. And, in fact, did you cite this 9 article in connection with your opinions and 10 recitation concerning both erosions and fistulas 11 caused by polypropylene slings in women? 12 A. I did. 13 Q. The second one that Mr. Snell asked 14 you about today was Exhibit No. 26, which was 15 "Long-Term Results of the Tension-Free Vaginal Tape 16 Procedure in an Unselected Group: A Seven-Year 17 Follow-Up Study," correct? 18 A. Yes. 19 Q. Okay. And Mr. Snell, again, asked 20 you why that wasn't included in the efficacy table, 21 correct? 22 A. Correct. 23 Q. He didn't ask you whether it was 24 included in your -- the main thrust of your article,</p>

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<p>1 which was the safety concerns that were raised by</p> <p>2 polypropylene midurethra slings, did he?</p> <p>3 MR. SNELL: Objection, leading.</p> <p>4 A. He did not.</p> <p>5 Q. Okay. And if you look at Footnote</p> <p>6 No. 227 in your "Nature" article, did you, in fact,</p> <p>7 rely on and cite this particular article identified</p> <p>8 by Mr. Snell in part of your safety analysis?</p> <p>9 A. I did.</p> <p>10 Q. No. 27 is an article entitled,</p> <p>11 "Long-Term Efficacy of Tension-Free Vaginal Tape in</p> <p>12 the Management of Stress Urinary Incontinence in</p> <p>13 Women Efficacy at 5 and 7-year follow-up." Do you</p> <p>14 see that?</p> <p>15 A. I do.</p> <p>16 Q. And, once again, Mr. Snell asked you</p> <p>17 why this was not included in Table No. 1 concerning</p> <p>18 efficacy, correct?</p> <p>19 A. Correct.</p> <p>20 (There is a discussion off the record.)</p> <p>21 Q. He did not ask you whether this</p> <p>22 particular article was cited in your "Nature" review</p> <p>23 concerning the safety aspects of polypropylene</p> <p>24 midurethral slings, did he?</p>	<p>1 say that you relied on the article concerning the</p> <p>2 TVT-O for the treatment of stress urinary</p> <p>3 incontinence in your review article?</p> <p>4 A. Yes, I did.</p> <p>5 Q. Now, there was also a lot of</p> <p>6 discussion about why certain articles were included</p> <p>7 and excluded from Table 1 concerning efficacy.</p> <p>8 The fact that they were not contained in</p> <p>9 exhibit or Table 1 concerning efficacy does not mean</p> <p>10 that you and your colleagues didn't consider them</p> <p>11 for your safety analysis, does it?</p> <p>12 MR. SNELL: Objection, calls for</p> <p>13 speculation.</p> <p>14 A. No, to the contrary. We cited it and</p> <p>15 did consider it for safety.</p> <p>16 Q. Okay. And, with respect to Table 1,</p> <p>17 am I correct that you only included the most recent</p> <p>18 published article from a particular cohort and not</p> <p>19 all of the interim studies?</p> <p>20 MR. SNELL: Actually, leading,</p> <p>21 objection.</p> <p>22 A. Yes.</p> <p>23 Q. And, for example, is it correct you</p> <p>24 only included Dr. Nilsson's 2013 paper, correct?</p>
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<p>1 A. He did not.</p> <p>2 Q. And, in fact, at Footnote No. 74, you</p> <p>3 cite to this very article in connection with your</p> <p>4 analysis of the safety of polypropylene midurethral</p> <p>5 slings, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And, in fact, you looked at this</p> <p>8 article in connection with your opinions on</p> <p>9 bacterial cystitis, perforations, voiding</p> <p>10 dysfunction and urethral obstructions, correct?</p> <p>11 A. Yes.</p> <p>12 MR. SNELL: Leading.</p> <p>13 Go ahead.</p> <p>14 Q. There was also a discussion of Dr.</p> <p>15 Serati's article last week. Do you recall that?</p> <p>16 A. Not specifically, no.</p> <p>17 Q. Do you know whether you relied on Dr.</p> <p>18 Serati's article in your "Nature" review?</p> <p>19 A. I don't know how to spell his name.</p> <p>20 Q. S-e-r-a-t-i.</p> <p>21 A. I do remember that now, yes. I mean,</p> <p>22 I remember reading it.</p> <p>23 Q. And if you look at Footnote No. 18,</p> <p>24 which refers to Dr. Serati's article, is it fair to</p>	<p>1 A. That's correct.</p> <p>2 Q. But you knew that there were earlier</p> <p>3 papers that came out from his cohort, correct?</p> <p>4 MR. SNELL: Objection, leading.</p> <p>5 Go ahead.</p> <p>6 A. Yes. And my recollection is we even</p> <p>7 discussed those in the paper itself.</p> <p>8 Q. Right. And you discussed those in</p> <p>9 connection with the safety considerations, correct?</p> <p>10 A. Yes.</p> <p>11 Q. But you only included the last paper</p> <p>12 in the efficacy considerations, correct?</p> <p>13 A. Yes.</p> <p>14 MR. SNELL: Objection, leading.</p> <p>15 Go ahead.</p> <p>16 Q. Despite the fact that some of those</p> <p>17 papers came out more than five years after the</p> <p>18 cohort was commenced, correct?</p> <p>19 MR. SNELL: Objection, leading.</p> <p>20 A. Yes.</p> <p>21 Q. And was that because they were</p> <p>22 reporting on the safety cohort of women that were</p> <p>23 already discussed in the 2013 article?</p> <p>24 A. Yes.</p>

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<p>1 Q. Okay. Now, Mr. Snell asked you a</p> <p>2 number of hypothetical questions about additional 10</p> <p>3 studies or 12 studies that purportedly may not have</p> <p>4 been included in Table 1.</p> <p>5 He didn't identify all of those articles for</p> <p>6 you, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And, in the absence of the</p> <p>9 identification of those articles, you can't</p> <p>10 determine which articles, specifically, he's</p> <p>11 referring to, correct?</p> <p>12 A. Correct.</p> <p>13 Q. And you can't determine whether these</p> <p>14 hypothetical -- why these hypothetical -- let me...</p> <p>15 You can't determine whether these</p> <p>16 hypothetical articles even exist, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And you can't determine if they</p> <p>19 exist, why they were not included in the table in</p> <p>20 the absence of him identifying those, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Now, did you consider and read more</p> <p>23 articles than you actually cited in your "Nature"</p> <p>24 review article?</p>	<p>1 MS. FITZPATRICK: Objection.</p> <p>2 Q. -- provide --</p> <p>3 A. That's correct.</p> <p>4 MS. FITZPATRICK: Objection, asked</p> <p>5 and answered.</p> <p>6 Q. And you don't write pathology</p> <p>7 reports?</p> <p>8 MS. FITZPATRICK: Objection, asked</p> <p>9 and answered.</p> <p>10 A. That's correct.</p> <p>11 Q. And you have not published the</p> <p>12 findings of pathology reports for your patients,</p> <p>13 correct?</p> <p>14 MS. FITZPATRICK: Objection.</p> <p>15 A. That's correct.</p> <p>16 Q. Meaning, you haven't written an</p> <p>17 article submitted to peer review as to the pathology</p> <p>18 findings of your patients, correct?</p> <p>19 MS. FITZPATRICK: Objection.</p> <p>20 A. Correct.</p> <p>21 Q. You haven't done that for your</p> <p>22 pubovaginal sling patients, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you haven't done that for</p>
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<p>1 MR. SNELL: Objection, vague.</p> <p>2 A. For -- for what? I don't understand</p> <p>3 the question.</p> <p>4 Q. Fair enough. That was a bad</p> <p>5 question.</p> <p>6 In your work dealing with women who have</p> <p>7 pelvic mesh complications, writing articles,</p> <p>8 reviewing articles for journals and in your work in</p> <p>9 preparing your expert reports in this case, have you</p> <p>10 considered more articles than are actually cited</p> <p>11 just in the "Nature" article itself?</p> <p>12 A. I have.</p> <p>13 Q. That's all that I have.</p> <p>14 MR. SNELL: Alright. I just have a</p> <p>15 few follow-up. And let's stop to take a break. I</p> <p>16 want to find something in here real quick.</p> <p>17 (Recess taken 3:39 to 3:42 p.m.)</p> <p>18 EXAMINATION BY MR. SNELL:</p> <p>19 Q. Doctor, a follow-up on some of the</p> <p>20 questions you were asked, some questions about</p> <p>21 pathology.</p> <p>22 Am I correct that you're not credentialed</p> <p>23 here at your hospital to read and interpret</p> <p>24 pathology slides that --</p>	<p>1 midurethral sling patients, correct?</p> <p>2 A. Correct.</p> <p>3 MS. FITZPATRICK: Objection, vague.</p> <p>4 Q. You mentioned that you were an editor</p> <p>5 of a journal and that you believe had some bearing</p> <p>6 on your opinions.</p> <p>7 Remind me of what journal that was? Was</p> <p>8 that the Journal of Neurourology and Voiding</p> <p>9 Dysfunction?</p> <p>10 A. And Uro --</p> <p>11 MS. FITZPATRICK: Objection.</p> <p>12 A. It's called Neurourology and Uro</p> <p>13 Dynamics.</p> <p>14 Q. Let me back up one minute.</p> <p>15 What journal did you refer to to which you</p> <p>16 were an editor?</p> <p>17 A. Neurourology and Uro Dynamics.</p> <p>18 Q. So you would have reviewed studies</p> <p>19 submitted to that -- strike that.</p> <p>20 You would have reviewed articles submitted</p> <p>21 to that journal?</p> <p>22 MS. FITZPATRICK: Objection, lacks</p> <p>23 timeframe, lacks a foundation.</p> <p>24 A. Yes, to that journal and also I</p>

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<p>1 mentioned many other journals as well.</p> <p>2 Q. When you were the editor of that</p> <p>3 particular journal, did you review all of the</p> <p>4 articles submitted to it?</p> <p>5 MS. FITZPATRICK: Objection, lacks</p> <p>6 foundation.</p> <p>7 A. I reviewed all of the abstracts and</p> <p>8 then depending upon the abstracts, I would make a</p> <p>9 judgment on whether or not I wanted to review the</p> <p>10 paper in detail. I was -- I was never a reviewer</p> <p>11 for an article unless I was asked to be by one of</p> <p>12 the editors. But I reviewed -- so I wasn't an</p> <p>13 official reviewer, but I reviewed, I mean, virtually</p> <p>14 all the articles on mesh because that was an</p> <p>15 interest of mine and I had final say over</p> <p>16 publication. So anytime there was a discrepancy,</p> <p>17 then I would review the article.</p> <p>18 Q. Is it your contention that every</p> <p>19 article that came out of that journal while you were</p> <p>20 editor is methodologically sound?</p> <p>21 A. I don't --</p> <p>22 MS. FITZPATRICK: Objection.</p> <p>23 A. No. It's not my contention at all.</p> <p>24 Q. Mistakes could have been made during</p>	<p>1 opinion in this case.</p> <p>2 A. Reporting complications is always</p> <p>3 valuable, but it doesn't give you a handle on what</p> <p>4 the incidence of the complications are or the</p> <p>5 likelihood of someone developing a complication.</p> <p>6 Q. So, you know Ed McGuire, right?</p> <p>7 A. I do.</p> <p>8 Q. Have you read some of his articles on</p> <p>9 autologous pubovaginal slings?</p> <p>10 A. I have.</p> <p>11 Q. Have you seen they actually had sling</p> <p>12 exposures -- strike that -- sling erosions with the</p> <p>13 autologous pubovaginal sling, right?</p> <p>14 A. I'm not aware of that.</p> <p>15 Q. Okay.</p> <p>16 A. It doesn't mean it didn't happen.</p> <p>17 Q. Fair enough.</p> <p>18 The Journal of Neurourology, why did they</p> <p>19 ask you to step down as editor at the meeting in</p> <p>20 Italy?</p> <p>21 MS. FITZPATRICK: Objection, lacks</p> <p>22 foundation, hypothetical, assumes facts not in</p> <p>23 evidence.</p> <p>24 MR. SNELL: It's not hypothetical.</p>
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<p>1 the editorial process while you were editor of that</p> <p>2 journal, right?</p> <p>3 MS. FITZPATRICK: Objection, beyond</p> <p>4 the scope, lacks a foundation, hypothetical.</p> <p>5 A. "Mistakes" are always possible. But</p> <p>6 the problems -- the "mistakes" are possible, but</p> <p>7 more often than not if a paper reported on efficacy</p> <p>8 -- if the primary objective of the paper was to</p> <p>9 report on efficacy and that was acceptable, then we</p> <p>10 -- in general, they wouldn't reject the article</p> <p>11 because of that and they would let the complication</p> <p>12 part stand because the complications they do report</p> <p>13 are valuable contributions to the literature. If we</p> <p>14 didn't do that, then there would be no complications</p> <p>15 reported to the literature and that would be even</p> <p>16 worse. I don't consider those "mistakes." I</p> <p>17 consider those, you know, prudent and practical</p> <p>18 compromises that editorial staff has to take.</p> <p>19 Q. So complications being reported in</p> <p>20 the literature, is that a beneficial thing in your</p> <p>21 opinion?</p> <p>22 MS. FITZPATRICK: Objection,</p> <p>23 hypothetical, lacks -- hang on -- hypothetical,</p> <p>24 lacks foundation, beyond the scope of his expert</p>	<p>1 MS. FITZPATRICK: You've got no</p> <p>2 foundation.</p> <p>3 A. I'm not aware that they asked me to</p> <p>4 step down at the meeting in Italy.</p> <p>5 Q. Okay. Did they ask you to step down</p> <p>6 as editor of that journal?</p> <p>7 A. Who is -- I don't know who you mean</p> <p>8 by "they."</p> <p>9 Q. Was there a vote of confidence on you</p> <p>10 in your role as editor of that journal?</p> <p>11 A. I'm not aware of that.</p> <p>12 Q. And it's your contention -- were you</p> <p>13 asked to step down as editor of that journal?</p> <p>14 A. By whom?</p> <p>15 Q. By anyone.</p> <p>16 A. There were people -- like anybody</p> <p>17 else, there were people that would like to see me</p> <p>18 not be editor. But I think you can say that about</p> <p>19 anybody in a public position.</p> <p>20 Q. But you did step down from that</p> <p>21 journal, correct?</p> <p>22 A. After 20 something years, yes.</p> <p>23 Q. And it was following a vote at a</p> <p>24 meeting in Italy; is that correct or not?</p>

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<p>1 MS. FITZPATRICK: Objection, asked 2 and answered, hypothetical, assumes facts not in 3 evidence. This has already been responded to by Dr. 4 Blaivas and this is pure harassment at this point. 5 A. You know what, I'm not aware of that. 6 I mean... 7 Q. Okay. That's fair enough. 8 When you were editor of that journal, did 9 you review the minutes of meetings coming out of 10 board meetings and other committee meetings? 11 A. Board meetings of whom? 12 Q. Of members of the journal, the 13 editorial staff. 14 A. Of course. 15 MS. FITZPATRICK: Hang on. Give me a 16 chance. 17 THE WITNESS: Okay. 18 MS. FITZPATRICK: Objection, beyond 19 the scope, irrelevant to what it is we're discussing 20 here, hypothetical. 21 (There is a discussion off the record.) 22 MR. SNELL: I'm just going to be 23 quick. 24 Q. Plaintiffs' counsel asked you some</p>	<p>1 Q. Do you recall us having a discussion 2 about that during my initial questioning? 3 A. I did, I do. 4 Q. Okay. Can I see that back really 5 quick? 6 A. Its yours. 7 Q. Well, we're sharing it. 8 Plaintiffs' counsel just showed you the 9 Footnote 18 by Serati, TVT-O five-year follow-up. 10 Do you recall that? 11 A. I do. 12 Q. Do you recall that the article, 13 actually, showed you was the ten-year TVT retropubic 14 follow-up, correct? 15 A. I don't recall it independently, but 16 I'll accept it from a... 17 Q. And we'll stop. I think I might be 18 done. 19 You mentioned that sometimes and then very 20 frequently you would ask for a revised pathology 21 report to be issued concerning one of your patients. 22 Do you recall giving that testimony? 23 A. Yes. 24 Q. In what percentages of your cases do</p>
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<p>1 questions about the review and she seems to 2 insinuate that I didn't ask you about anything other 3 than Table 1, the long-term. 4 But, Doctor, actually, you and I discussed 5 quite a bit Table 3, "Complications of Retropubic 6 Slings," didn't we? 7 A. Yes, we did. 8 Q. And that's where you reported the 9 less than 1 percent rate of women who had pain 10 lasting six weeks or more with the TVT, right? 11 A. I didn't report that. I read what 12 other reportedly constructed studies have shown. 13 Q. That's what you wrote down in your 14 paper, though, correct? 15 A. We -- yes, I just answered that. 16 Q. Okay. And you and I discussed 17 vaginal exposures, too, that you reviewed, right? 18 A. Yes. 19 Q. And you were asked questions about 20 infection and you and I also discussed and you wrote 21 in your review that the rate of serious infection in 22 combination with bowel perforations was less than 23 what, Doctor? It's highlighted on the right side. 24 A. Of about 0.1 percent.</p>	<p>1 you ask for revised pathology reports? 2 A. I would say in most cases I have a 3 question for them. It doesn't always relate to 4 asking them to revise it. But, I mean, the problem 5 is they don't -- you know, they don't routinely do 6 things that would be useful -- would be useful for, 7 basically, for our research because we're not, you 8 know, they're looking -- they look at the pathology 9 differently than we do. I mean, in fairness, I 10 don't think anybody is doing anything wrong. I 11 think their goal of looking at pathology is to make 12 sure that there's not cancer or, in fact, we're 13 giving them a proper specimen. And our goal is to 14 try to understand better about the physiology and 15 pathophysiology of all these things. But it really 16 doesn't necessarily -- it doesn't change how we 17 treat the patient. It changes how we understand how 18 they got there. 19 Q. Yeah. 20 A. So they don't -- it's just a 21 different frame of reference. 22 MR. SNELL: [MOTION] I'm going to, 23 very respectfully, move to strike as nonresponsive. 24 MS. FITZPATRICK: I'm going to object</p>

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<p>1 to the motion to strike.</p> <p>2 MR. SNELL: Can you reread the</p> <p>3 question to the Doctor.</p> <p>4 Q. And I'm focused on what is the</p> <p>5 percent. But I'll let Madam court reporter read it</p> <p>6 back.</p> <p>7 (Whereupon, the question is read back as</p> <p>8 follows:</p> <p>9 "Question: In what percentages of your</p> <p>10 cases, do you ask for revised pathology reports?")</p> <p>11 A. I don't have independent knowledge,</p> <p>12 but I would say less than half but more than</p> <p>13 single-digit percents. I just couldn't estimate</p> <p>14 better than that.</p> <p>15 Q. Okay. Okay. I'm done. Thank you.</p> <p>16 MS. FITZPATRICK: I have one question</p> <p>17 based on that, maybe two.</p> <p>18 EXAMINATION BY MS. FITZPATRICK:</p> <p>19 Q. Dr. Blaivas, have you personally ever</p> <p>20 seen a woman who had an erosion with a pubovaginal</p> <p>21 or an autologous sling?</p> <p>22 A. No.</p> <p>23 Q. Have you talked to your colleagues</p> <p>24 about any problems that they have had with erosion</p>	<p>1 international meetings. And every one of them has</p> <p>2 something about mesh complications and mesh erosion</p> <p>3 so...</p> <p>4 Q. Okay. That's all that I have.</p> <p>5 MR. SNELL: I'm going to follow up on</p> <p>6 that.</p> <p>7 EXAMINATION BY MR. SNELL:</p> <p>8 Q. Well, I showed you in your own AUA</p> <p>9 guidelines Table A16 revised 2012 where you and a</p> <p>10 whole bunch of other urologists reported autologous</p> <p>11 fascia without bone anchors.</p> <p>12 So that's a non-synthetic procedure, right?</p> <p>13 A. Yes.</p> <p>14 Q. And you reported, "erosion extrusion</p> <p>15 1 percent," and below that it says, "erosion</p> <p>16 extrusion into the urethral-bladder 2 percent."</p> <p>17 So it has been reported even by you,</p> <p>18 correct?</p> <p>19 A. I don't believe any of the people --</p> <p>20 this was -- yes, it's been reported. But I don't</p> <p>21 believe that any of us acknowledged that it happens</p> <p>22 with that frequency.</p> <p>23 The problem is I alluded to before is that</p> <p>24 we were constrained by the AUA -- overall AUA</p>
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<p>1 caused by pubovaginal or autologous slings?</p> <p>2 A. Never.</p> <p>3 Q. Do you believe that an erosion is a</p> <p>4 common complication or even a rare complication of</p> <p>5 pubovaginal or autologous sling?</p> <p>6 MR. SNELL: Objection.</p> <p>7 A. No, I do not.</p> <p>8 Q. Okay. And why not?</p> <p>9 A. I answered part of it before.</p> <p>10 Because, you know, we -- over the years we probably</p> <p>11 -- I would say I have lectured before just in small</p> <p>12 groups I would say, at least, 5,000 different</p> <p>13 urologists and gynecologists, which is, you know, by</p> <p>14 today's numbers half of all urologists in the</p> <p>15 country and it never once came up. And we get</p> <p>16 questions about -- we get questions about mesh</p> <p>17 fistulas, which by my own account is less than 1</p> <p>18 percent. So people, actually, ask me, well, how do</p> <p>19 you manage mesh fistulas?</p> <p>20 It's inconceivable to me that if this was a</p> <p>21 common problem, not one person ever would have asked</p> <p>22 me about an erosion and it was never ever not once</p> <p>23 brought up in any of our meetings. I've never seen</p> <p>24 it ever once presented at any of our national or</p>	<p>1 guidelines panel -- by the overall guidelines panel</p> <p>2 committee on a certain methodology to, you know, in</p> <p>3 our reporting. So, if these things were reported in</p> <p>4 the literature, we couldn't say that they -- we</p> <p>5 couldn't ignore it.</p> <p>6 But thanks to your questioning from last</p> <p>7 time, I had the opportunity to go back and read some</p> <p>8 of the papers that actually alluded to this. And</p> <p>9 what I found was that many of the studies that used</p> <p>10 -- many of the reported studies about autologous</p> <p>11 slings eroding or perforating used a methodology --</p> <p>12 a flawed methodology that I've been critical of with</p> <p>13 -- that the TVT introduced. And that is blind</p> <p>14 passage of trocars to pass the instruments to put</p> <p>15 the sling in place. So what I believe happened is</p> <p>16 the newer studies using autologous slings utilized a</p> <p>17 flawed technique introduced by the TVT and,</p> <p>18 therefore, suffered some of the same complications</p> <p>19 that the TVT -- that the TVT had. When you compare</p> <p>20 -- when you look at the studies that used what we</p> <p>21 call full-length autologous slings, in using the</p> <p>22 technique, for example, that I described, I don't</p> <p>23 believe there is a single case report in the world</p> <p>24 literature about that. And even if there was, as I</p>

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<p>1 already mentioned, it's extraordinarily rare and of</p> <p>2 little consequence and even if every one of these --</p> <p>3 I don't believe they were, but even if every one of</p> <p>4 these reported complications was a legitimate</p> <p>5 complication of an autologous sling, even if that</p> <p>6 were the case, the repercussions are almost nothing.</p> <p>7 All you -- compared to a mesh sling. So the net</p> <p>8 effect is what I already testified to a moment ago.</p> <p>9 So I'm not going to repeat it.</p> <p>10 Q. Well, Doctor, I think you just said</p> <p>11 that the blind passage of instruments or trocars was</p> <p>12 introduced by TVT.</p> <p>13 You and I both know that surgeons were</p> <p>14 passing blindly surgical instruments to put in</p> <p>15 autologous pubovaginal sling long before TVT, right?</p> <p>16 MS. FITZPATRICK: Objection,</p> <p>17 mischaracterizes and misstates the testimony.</p> <p>18 A. Not -- well, there's a difference --</p> <p>19 Q. Can you answer my question yes or no?</p> <p>20 A. Not since -- to my knowledge, the</p> <p>21 overwhelming majority -- I can't say never. But the</p> <p>22 overwhelming majority of autologous slings were done</p> <p>23 by the technique that was described either by Dr.</p> <p>24 McGuire or myself. And neither of us used trocars</p>	<p>1 MS. FITZPATRICK: Objection,</p> <p>2 mischaracterizes the testimony.</p> <p>3 A. I understand the question.</p> <p>4 I used Stamey needle only for the synthetic</p> <p>5 sling when I temporarily bought into the idea that</p> <p>6 this might be a good technique. I never once ever</p> <p>7 used anything other than something called a long</p> <p>8 Debakey clamp, which is not a trocar, which does not</p> <p>9 have a point. That's the only instrument I've ever</p> <p>10 used for an autologous sling.</p> <p>11 Q. You said you read some of these</p> <p>12 papers on autologous slings. What are the names of</p> <p>13 those papers that you read?</p> <p>14 A. I don't have an independent</p> <p>15 recollection of it right now.</p> <p>16 MS. FITZPATRICK: Objection.</p> <p>17 Can we check the time?</p> <p>18 Q. How many of them did you read?</p> <p>19 A. Five.</p> <p>20 MS. FITZPATRICK: Let's take a minute</p> <p>21 to check the time.</p> <p>22 (There is a discussion off the record.)</p> <p>23 A. I want to correct my last answer. I</p> <p>24 think I said five at the end. I didn't mean -- I do</p>
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<p>1 and things like that. We used -- the dissection was</p> <p>2 done with our finger -- the way -- I've already</p> <p>3 testified to the way it was done. So now the Roz</p> <p>4 (phonetic) technique did -- the Roz (phonetic)</p> <p>5 technique not for slings but the Roz (phonetic)</p> <p>6 technique for -- I'm trying to -- that he used for</p> <p>7 his repair -- for his incontinence operations, that</p> <p>8 did use a small trocar and that did have that</p> <p>9 complication sometimes. But that's not the</p> <p>10 technique for autologous slings.</p> <p>11 Q. You were using needles blindly for</p> <p>12 your autologous pubovaginal slings long before TVT,</p> <p>13 right?</p> <p>14 A. I never --</p> <p>15 MS. FITZPATRICK: Objection,</p> <p>16 mischaracterizes the testimony.</p> <p>17 A. The answer is, no, I don't believe I</p> <p>18 ever used one.</p> <p>19 Q. What instrument did you use? I</p> <p>20 thought you told me you used Stamey needle --</p> <p>21 A. No.</p> <p>22 Q. -- or some other type of needle to</p> <p>23 pass your sling to go down and pull it back up.</p> <p>24 A. Okay.</p>	<p>1 have a recollection. I read all of the references</p> <p>2 relating to erosions that were referenced in the</p> <p>3 Schimpf article that you brought to my attention</p> <p>4 last time. But I don't remember right now the</p> <p>5 individual papers.</p> <p>6 Q. Did you go back and read all the</p> <p>7 articles cited in the AUA paper?</p> <p>8 A. No, but I did review some of them.</p> <p>9 Q. You mentioned that you do a</p> <p>10 full-length autologous sling. When you say,</p> <p>11 "full-length," what do you mean by that?</p> <p>12 A. It means that it's long enough --</p> <p>13 there isn't a specified length, but it's long enough</p> <p>14 to go from well into the retropubic space on one</p> <p>15 side and around to the other side. And, usually, it</p> <p>16 goes to just underneath the rectus fascia on one</p> <p>17 side to just underneath the rectus fascia on the</p> <p>18 other side.</p> <p>19 Q. Is there an average length? Are we</p> <p>20 talking 10 centimeters, 20 centimeters?</p> <p>21 A. Yeah, I would say -- I would say</p> <p>22 average maybe 10 or 12.</p> <p>23 Q. Okay.</p> <p>24 A. It depends on how big the person is.</p>

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